Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1741 – Continuous nerve blockade using a catheter technique

Applicant:	Australian Society of Anaesthetists
Applicant.	Australian Society of Anaesthelists

Date of MSAC consideration: 4-5 April 2024

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, <u>visit the</u> <u>MSAC website</u>

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of continuous peripheral nerve block (CNB) for moderate to severe pain after surgery was received from the Australian Society of Anaesthetists by the Department of Health and Aged Care.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness, and total cost, MSAC supported the creation of a new MBS item for CNB for the management of moderate to severe post-operative pain. MSAC considered that despite the limited and uncertain evidence there was probably a small but important benefit compared to single nerve block (SNB) or systemic opioids. There may potentially be other downstream benefits, including reducing opioid use. MSAC considered the economic evaluation made it difficult to assess relativities as it described the cost per pain unit on a visual analogue scale, but was unlikely to be improved due to the limited data and on balance was sufficient for decision-making. The financial impact to the MBS was modest although the extent of substitution of CNBs for current SNBs was uncertain. Utilisation should be monitored two years post implementation. MSAC considered that no evidence was presented regarding non-operative use of CNB, and therefore it could not advise on extending the supported service to include this indication. MSAC considered the appropriate fee should be set at 4 basic units based on other relative value guide services with comparable complexity.

MSAC's supported item descriptor is provided below (Table 1).

Table 1 MSAC's supported MBS item descriptor

Category 3 – THERAPEUTIC PROCEDURES
Group T10 – Relative Value Guide For Anaesthesia – Medicare Benefits Are Only Payable For Anaesthesia Performed In Association With An Eligible Service
Subgroup 19 – Therapeutic And Diagnostic Services
MBS item AAAA
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 (4 basic units).
(See para TN.10.17 of explanatory notes to this Category)
Fee: \$87.20 Benefit: 75% = \$65.40

Note: 75% benefit is payable for treatment of hospital inpatients. \$87.20 represents 4 units as at 1 November 2023.

Consumer summary

This was an application from the Australian Society of Anaesthetists requesting Medicare Benefits Schedule (MBS) listing of continuous peripheral nerve block for moderate to severe pain after surgery.

Nerves are like the electrical wires of the body, passing signals and information (such as pain or temperature) from the body to the brain, where the information is interpreted and felt by the person. A nerve block is a procedure to relieve pain and involves medicine such as a local anaesthetic being injected around a nerve to prevent pain signals from reaching the brain and stop a person feeling pain. This leads to numbing of specific areas of the body. Nerve blocks can last for a short amount of time (such as a single-injection nerve block) or be longer lasting. This application proposed MBS funding of a continuous peripheral nerve block, which is used for longer-lasting pain relief. "Peripheral" means it is for nerves located outside of the brain and spinal cord, such as in the arm or leg.

Continuous peripheral nerve block involves the insertion of a catheter (a thin, flexible tube) next to the target nerve, which is then used to deliver a continuous flow of pain medication to the affected nerve. Continuous nerve block was proposed as an alternative to current approaches such as a single injection nerve block or opioid medication such as morphine. This application was for the use of a continuous peripheral nerve block around the time of surgery (perioperatively) to relieve pain following the surgery.

MSAC considered that, despite the limited and uncertain evidence, continuous nerve block appeared to provide a small but clinically important improvement in pain relief, compared to current options. MSAC also recognised that continuous nerve block may reduce the need for people to take opioid medication for their pain, which it considered to be of high importance because long-term use of opioids can lead to addiction in some people.

MSAC advised that continuous nerve block should have a slightly higher fee than singleinjection nerve block, aligning its cost with similar medical procedures. MSAC considered that continuous nerve block was a slightly more complex procedure than single-injection nerve block. While the economic assessment was done in a way that made it hard to measure the value for money, MSAC considered that the value for money was acceptable. It is likely that many patients who would have had single-injection nerve blocks would have continuous nerve blocks instead, but MSAC considered that the amount of substitution was uncertain. This made the overall cost to the MBS a little uncertain, however MSAC advised the financial cost was modest and acceptable, and use should be monitored.

No evidence was presented on the use of continuous nerve block in situations other than surgery (such as injury), so MSAC could not advise on non-surgical use.

MSAC's advice to the Commonwealth Minister for Health and Aged Care

MSAC supported public funding of continuous peripheral nerve block for management of moderate to severe pain after surgery. Despite the limited evidence, MSAC considered that continuous nerve block provides a small benefit over alternative procedures and is likely good value for money. MSAC recommended that use of the service be reviewed after two years.

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

MSAC noted that this application from the Australian Society of Anaesthetists was requesting Medicare Benefits Schedule (MBS) listing of continuous peripheral nerve block (CNB) for moderate to severe pain after limb or trunk surgery.

MSAC recalled that, at its meeting in April 2017, it had considered application 1308¹ for local anaesthetic nerve blockade for surgical analgesia. MSAC recalled it had not supported this application at the time due to multiple issues and considered overall that the current application had addressed most of these issues.

MSAC noted that consumer feedback was received from two professional organisations and six specialists, with feedback being supportive overall. There was support for reducing the use of opioids. Additionally, one specialist commented that there is evidence that CNB reduces post-traumatic stress disorder in military personnel. MSAC noted one respondent stated that the current application did not propose a significant change from current practice, only a change in claiming, with little notable benefit. MSAC noted that CNB is now approaching standard of care for several types of major joint surgery.

MSAC noted that the pre-MSAC response requested that the service be funded for use in both the operative and non-operative (such as injury) settings. MSAC considered that, although CNB may also potentially be useful in the non-operative setting, no evidence had been provided for non-operative settings, therefore it was unable to advise on non-operative CNB. MSAC noted existing MBS items for non-operative nerve blocks do not specify the use of catheters.

MSAC noted the clinical claim was that CNB is superior in effectiveness and non-inferior in safety compared to single-injection nerve block (SNB).

MSAC noted that, based on uncertain evidence, the department-contracted assessment report (DCAR) found CNB to have superior effectiveness and non-inferior safety relative to both SNB and systemic opioids in patients undergoing knee surgery associated with moderate to severe postoperative pain expected to last 12 hours or longer. For safety, this included less nausea and vomiting at 48 and 72 hours when compared to systemic opioids, but there was no difference compared to SNB. For effectiveness, this included lower breakthrough opioid consumption, reduced chronic pain at three and six months, and fewer block failures/reattempts when compared to systemic opioids. It also included superior (or mixed) results for patient-reported pain scores and patient satisfaction compared to SNB; however, MSAC noted that, although outcomes such as reduced opioid consumption were reported with CNB, these outcomes were assessed at 48 hours and did not translate to superior patient outcomes at 48-72 hours. Additionally, pain - which was assessed using a 10-point visual analogue scale (VAS) - was found to be reduced by a mean of 1.35 points, which was near the lower threshold for a minimal clinically important difference (MCID; equivalent to 1.5 on a 10-point VAS). MSAC noted that there was insufficient evidence to draw conclusions on the relative effectiveness and safety of CNB compared to neuraxial nerve block. MSAC noted there was the potential for patients to have a shorter length of stay in hospital: MSAC considered this was supported by published guidance for patients on how to remove the catheter themselves, but that any reduction in length of stay was uncertain and may vary between CNB indications. Overall, MSAC considered that CNB likely provides a small but important clinical benefit for pain relief with low confidence, and so advised that it was acceptably clinically effective. MSAC also considered it may reduce opioid use and lead to other downstream benefits.

MSAC raised whether CNB should be restricted to indications where single-injection or neuraxial nerve block would not be effective but considered that a decision between CNB and SNB is an

¹ <u>http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1308-public</u>

individual clinical decision between the clinician and the patient. MSAC therefore did not consider it was appropriate to restrict CNB to only patients who cannot receive SNB or neuraxial block.

MSAC noted that CNB would be used for a wide variety of surgical indications, but the DCAR examined the exemplar case of knee surgery, supplemented by systematic reviews for other indications where possible. MSAC considered that there was insufficient evidence for the use of CNB for indications other than the exemplar (knee surgery), and for patient-centred outcomes/experience, quality of life (QoL), data on length of hospital stay, and other value-based care aspects such as overall costs and clinical benefits of the procedure. However, MSAC considered that sufficient evidence and adequate patient-reported measures were not likely to be forthcoming due to the heterogeneity of the indications.

MSAC noted that the economic evaluation was a cost-effectiveness analysis using a decision tree model and a time horizon of five days. MSAC noted that the PICO stated that a cost-utility analysis would be appropriate, but the DCAR stated this was infeasible due to the available evidence and short time horizon. MSAC noted that the incremental cost per one unit of improvement in pain (versus SNB), measured using a VAS, was \$114.35. The primary drivers of the model were the cost of the catheter and costs for anaesthesia consultation (for catheter management). MSAC noted that there was no ability to model long-term reduction in opioid use when using CNB. There was no modelling provided for health-related quality of life or chronic pain. MSAC considered there was uncertainty in how well the economic modelling of the exemplar case would generalise to other types of surgery that this item would also apply to, however on balance MSAC considered the economic evaluation was sufficient for it to be confident that CNB was acceptably cost-effective.

MSAC noted that SNB, the main comparator, is currently reimbursed under MBS item 22041 with a fee of \$43.60, which represents two basic units of the relative value guide (RVG). MSAC noted that the item descriptor for 22041 does not reference "single injection" or the use of a catheter, so anaesthetists who insert a catheter for CNB may currently be claiming existing item 22041 when performing CNB. MSAC noted that CNB is a variation of the SNB technique and requires the placement of a catheter adjacent to a peripheral nerve or nerve plexus. In line with the MBS Review Anaesthesia Clinical Committee's advice, MSAC considered CNB to be a more challenging procedure than SNB.

MSAC further noted that the RVG is based on complexity and this specific item does not include a premium for efficacy, although effectiveness does rely on finding the nerve and putting the block in the right place. MSAC noted that the applicant had proposed a fee of \$109.00 corresponding to five basic units, but that the MBS Review Anaesthesia Clinical Committee had advised that the complexity of the procedure warranted four basic units. MSAC considered that the complexity and effectiveness of a nerve block procedure was related to identifying nerves and placing the block in the correct position, and the placement of a catheter did not warrant three units more complexity than SNB. MSAC considered that a neuraxial block with or without catheter insertion (MBS item 22031; fee of \$109.00, which represents five basic units, corresponding to a current fee of \$87.20, was appropriate for the proposed CNB procedure. MSAC also noted that follow-up requirements may exist for both SNB and CNB, and these are already funded by other MBS items.

MSAC noted that it may not be possible to insert a catheter beyond the knee or elbow, and considered it was not necessary to specify the sites for CNB, supporting a site-agnostic item descriptor (Table 1).

MSAC noted that in the pre-MSAC response the applicant disputed the costs for SNB, stating that, because ultrasound will also be used for the comparator, ultrasound costs should have

been included. However, MSAC considered that there should not be an added fee for ultrasound because it forms part of the package of care.

MSAC noted that there was a gap of \$206.88 between the estimated cost for a CNB (\$315.88, which includes the cost of a disposable pump) and the proposed MBS fee (\$109.00). Reducing the MBS fee increased the gap to \$228.68. MSAC noted that there were no data on out-of-pocket costs for the comparator, so the base case assumed they were equal to the out-of-pocket cost for the intervention. For MBS item 22031, in the private setting in 2021–2022, 98% of services involved out-of-pocket costs, typically \$204. No out-of-pocket cost data were available for MBS item 22041. MSAC noted that, in their comments on the ratified PICO confirmation, the applicant clarified that the estimated cost for the service (at the time, \$303.56) was an estimated maximum charge for the service and incorporated the cost of catheters, which are currently paid for by hospitals. The applicant had stated that the figure was "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 applicant had also stated that "the [Australian Society of Anaesthetists] 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". MSAC considered that while funding CNB at four units may result in higher out-of-pocket costs for patients than funding it at five units, four units was the appropriate fee based on complexity, and that MSAC can advise on the MBS fee but does not determine the out-of-pocket cost to patients. MSAC considered there remained a risk of out-of-pocket costs for patients, and questioned whether publicly funding this service will improve equity, although on balance considered public funding was more likely to improve equity of access.

MSAC noted that the DCAR estimated there would be 28,758 CNBs in year 1 increasing to 36,703 in year 6, and that service volumes would be partially offset by SNBs being replaced (MBS item 22041). MSAC noted the DCAR estimated the net financial impact to the MBS to be \$1.98 million in year 1 increasing to \$2.53 million in year 6. MSAC considered the extent of replacement of SNBs was uncertain, and also questioned whether funding this service will drive more CNBs to be performed, recommending that this be monitored. MSAC also considered it appropriate to have a 75% benefit only, as this service is intended for inpatients. MSAC noted from sensitivity analyses that if 22% of services used a catheter, the financial impact to the MBS could be as much as \$2.62 million in year 1 to \$3.34 million in year 6. MSAC considered that the cost to the MBS would be lower than estimated in the DCAR as MSAC had supported a lower fee than was proposed, and while the extent of replacement and any increase in service volumes added uncertainty, overall, the financial cost to the MBS was acceptable.

MSAC recommended that utilisation be reviewed after two years, including the extent of replacement of SNBs and whether more services are performed after listing.

4. Background

The Medical Services Advisory Committee (MSAC) has previously considered continuous catheter blockade of peripheral nerves for postoperative pain management in the context of a broader application (MSAC application 1308) encompassing minor, major and continuous peripheral nerve blocks in April 2017. The application 1308 was not supported by MSAC due to several concerns highlighted in Table 2.

MBS item 22041 for perioperative plexus or nerve block, without catheter insertion, proximal to the lower leg or forearm was introduced on the MBS from 1 November 2019 in line with the recommendations of the MBS Review Taskforce Anaesthesia Clinical Committee.²

² Anaesthesia Clinical Committee. 2017. *MBS Review – Final taskforce reports, findings and recommendations* [Online]. Available at: <u>https://www.health.gov.au/resources/publications/taskforce-endorsed-report-anaesthesia-clinical-committee?language=en</u>

Table 2 Sumn	nary of key	matters of	concern
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Component	Matter of concern	How the current assessment report addresses it
Background (the service, intended purpose), Approach to assessment	MSAC suggested only LANBs with demonstrable and clinically significant health outcome benefits to patients and the healthcare system should be considered (PSD, p.1)	Addressed. The population has been restricted to patients with a higher need (i.e. with moderate to severe postoperative pain lasting more than 12 hours).
Background (the service, intended purpose), Approach to assessment	MSAC suggested to identify 'high value' nerve blocks that have or are likely to have clear benefits to determine their effectiveness, safety and cost-effectiveness (PSD, p.3)	Addressed. Only continuous nerve blocks were evaluated in this application. Due to changes in approved opioid uses, there is an increased clinical need for alternatives for the management of acute postoperative pain.
Results of assessment	MSAC was concerned about the inclusion of all types of peripheral nerve blocks to the MBS list based solely on evidence of a representative nerve block within a category (PSD, p.2).	Addressed. The application was not restricted to specific types of nerve blocks, which is consistent with the existing MBS item (22041) for single-injection nerve blocks.
Background (Existing services) and Approach to assessment (Comparator)	MSAC advised the nominated comparator should be 'no block' in any resubmission, but noted that active comparators (e.g. local infiltration or joint infiltration associated with joint replacement surgery) could also be available (PSD, p3).	Addressed. The current applicant's clinical claim was based on MBS item 22041 (subsequently listed) – perioperative introduction of a plexus or nerve block proximal to the lower leg or forearm for postoperative pain management, which was considered in the current application as the main comparator. Additionally, the comparator 'no continuous block' was defined as a composite of existing treatment alternatives, instead of no block or placebo in application 1308, as patients with this indication will always be treated in clinical practice.
What are the economic considerations (Financial implications) and Discussion and	MSAC acknowledged the clinical need for LANBs but expressed concern about uncertainties in the clinical effectiveness and cost-effectiveness of various nerve block types, and the considerable uncertainty about the estimates of utilisation and financial impacts (PSD, p3).	Addressed. Only a subset of evidence relating to moderate to severe pain lasting more than 12 hours and using continuous blocks informed the current application. The main comparators were single-injection nerve block, neuraxial nerve block and systemic opioids. The proposed MBS item fee was calculated as 5 basic units, using the RVG. This proposed fee was used in the cost analysis.
What are the economic considerations (Background, Financial implications, and other cost considerations)	MSAC noted that an out-of-pocket cost was included, but the applicant strongly disagreed it would be common with LANB procedures (PSD, p3). ESC noted that anaesthesia costs were a frequent cause of unexpected expenses for patients (PSD, p10).	Not addressed. A difference of \$198.81 between the overall cost of a continuous nerve block (\$303.56) and the proposed MBS fee (\$109.00) was stated in application 1741. The extra cost coverage requires further investigation.

Component	Matter of concern	How the current assessment report addresses it
Results of assessment	MSAC suggested that evidence on other potential LANB advantages, such as hospital stay duration, recovery time, postoperative chronic pain and quality of life, could facilitate a cost-utility analysis to support the committee's decision-making process (PSD, p2). These data were scarce or missing in application 1308.	Partially addressed. Time to first mobilisation after surgery was assumed, although there was limited evidence. No health-related quality of life data were retrieved in the systematic literature review. Considering the lack of quality-of-life data, a cost-effectiveness analysis rather than a cost-utility analysis was performed.

Abbreviations: ESC = Evaluation Sub-Committee; LANB = local anaesthetic peripheral nerve block; MBS = Medicare Benefits Schedule; MSAC = Medical Services Advisory Committee; PSD = Public Summary Document; RVG = relative value guide for anaesthesia Source: DCAR Table 2

5. Prerequisites to implementation of any funding advice

No Therapeutic Goods Administration (TGA) approval or other prerequisites are required for this application. Continuous nerve blocks use medicines and equipment already approved by the TGA.

6. Proposal for public funding

The proposed technology, continuous nerve block, is a variation of the existing single-injection nerve block technique and requires the placement of a catheter adjacent to a peripheral nerve or plexus. Based on the deliberations of MSAC and the Anaesthesia Clinical Committee, this technique was considered more challenging than a single injection, requiring a new MBS item in Group 10 of the Relative Value Guide (RVG) for anaesthesia. The proposed MBS descriptor follows the wording of the existing Group T10/RVG items Nerve or Plexus Blocks for Post Operative Pain, and has been adjusted from the applicant's wording³ (Table 3 and Table 4). A definition of pain was not included in the item, as continuous nerve block is administrated preemptively in perioperative settings, based on clinical knowledge of expected postoperative pain.

Table 3 Continuous peripheral nerve block: proposed MBS item

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 AAAA

Perioperative introduction of a plexus or nerve block to a <u>peripheral</u> nerve, using an *in situ* catheter in association with anaesthesia and surgery, for post operative pain management of limb and trunk surgeries (5 basic units).

(See para TN.10.17 of explanatory notes to this Category)

Fee: \$109.00 Benefit: 75% = \$81.75

Note: 75% benefit is payable for treatment of hospital inpatients; 85% to all other services Source: DCAR Table 2

³ Yellow highlights indicate addition compared to the item descriptor as per the PICO document. The underlined word is the suggested change to the wording of the existing item on single-injection nerve block suggested by the applicant in the PICO document.

Table 4 Associated explanatory note

Category 3 – THERAPEUTIC PROCEDURES
TN.X.X
Item AAAA
Benefits are payable under item AAAA for perioperative introduction of a plexus or nerve block to a peripheral nerve, using an <i>in situ</i> catheter in association with anaesthesia and surgery, for post operative pain management of limb and trunk surgeries.
Benefit is not payable under this item for ultrasound guidance for injection or catheter insertion for anaesthesia.
Related Item: AAAA
Source: DCAR Table 3

The descriptor of item 22041, specific to single-injection nerve block for limb surgery has been amended by removing 'proximal to a lower leg or forearm' in the proposed descriptor, as continuous nerve blocks are intended to be used for limb and trunk surgery; 'peripheral nerve' has been added. Due to anatomical considerations, a catheter cannot be inserted 'distally to the lower leg and forearm'.

Anaesthetists or general practitioner (GP) anaesthetists would be the only healthcare providers entitled to claim this MBS item. A single claim would be able to be submitted per nerve block and multiple claims could be billed if bilateral or multiple continuous nerve blocks were required. Moreover, it would be necessary for continuous nerve block to always be delivered with anaesthesia and co-claimed with other anaesthesia-eligible items, in line with rules for other RVG nerve block items. In public hospitals, anaesthetists can claim an RVG item only if the service provided is part of their private practice within the public hospital, not as employees, as described in the MBS general explanatory note GN.12.30.

Only private patients, whether treated in public or private hospitals, were relevant for this application.

As the intervention falls under the RVG items, the proposed fee was evaluated based on the number of basic units, representing the complexity of the service. Continuous nerve block procedure was estimated for the application 1308 to value 4 to 5 basic units, based on the recommendations of the MBS Review's Anaesthesia Clinical Committee (which only considered limb surgery) and the Evaluation Sub-Committee (ESC), respectively. The applicant proposed a fee of \$109.00, which corresponds to the value of 5 basic units (current value of 1 basic unit: \$21.80). For reference, item 22041 – perioperative introduction of a plexus or nerve block proximal to the lower leg or forearm for postoperative pain management – without a catheter, is 2 basic units. Item 22031 – neuraxial block with or without insertion of a catheter – is 5 basic units.

In the ratified PICO,⁴ the applicant suggested that the actual cost for the service was expected to be \$303.56, which could result in additional costs for patients. Disposable elastomeric pump sets would be available in some cases, allowing for earlier hospital discharge or outpatient treatment, potentially covering the out-of-pocket expenses.

⁴Medical Services Advisory Committee. 2023. MSAC application 1741 Continuous nerve blockade using a catheter technique, ratified PICO confirmation. Available at: <u>http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1741-public</u>

7. Population

One PICO set was defined for this application. The target population was patients undergoing limb or trunk surgery (in- and outpatients), for whom acute pain is expected to be moderate or severe and last for more than 12 hours.

During the pre-anaesthesia assessment, the anaesthetist would decide whether a continuous nerve block is required. Continuous nerve block would only be administrated by specialist anaesthetists in a perioperative setting, either for elective or trauma limb or trunk surgery. In rural or regional hospitals, accredited and certified GP anaesthetists for the proposed intervention may be responsible for the assessment and placement of the continuous nerve block. After surgery, the patient's pain levels would be regularly assessed; the local anaesthetic dose could be adjusted accordingly, or additional analgesic could be given. Compared to systemic opioids, single-injection or neuraxial nerve blocks—which require a gradual change in pain management from higher strength, hospital-administered opioids to lower strength oral opioids taken at home—the proposed intervention does not generally require transition to oral opioids because continuous nerve blocks are intended to provide sustained relief of localised pain.

For inpatients, continuous nerve block would be set for 3 to 5 days according to surgical indication and the patient's prognosis. In very limited instances, such as traumatic amputation, the proposed intervention could be maintained for an extended time—30 days has been suggested by the applicant—pending assessment of the risks and benefits, and consideration of special catheter or alternative techniques.

Depending on their state of health, some patients could also be discharged earlier with a disposable pump filled with the local anaesthetic. The post-discharge management of outpatients receiving the intervention (including catheter self-removal), needs to be further explored. Once the catheter is removed—usually after 3 to 5 days—non-opioid oral analgesia would be provided.

8. Comparator

The comparators as per the PICO included single-injection nerve block (primary comparator) and secondary comparators, systemic opioids and neuraxial analgesia (spinal or epidural blocks) (Table 5). Their associations with additional analgesia (opioids \pm oral non-opioid analgesia) were also mentioned as potential comparators. The usage rate of these comparators differs with the type of surgery required and the patient's profile.

Given the level of pain experienced by patients following these surgical procedures, 'no continuous block' (i.e. placebo, standard care or sham plus any rescue medication) was not a relevant comparator for ethical reasons. Wound infiltration, which is for pain of a lower intensity, was also not a comparator for this application.

Comparators	Details	% estimated use (by target population)	Max duration	First follow- up treatment
Single-injection nerve block (primary comparator)	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. ^a	40–80%	12 hours	Systemic opioids (intravenous or oral) or non-opioid oral analgesics
Systemic opioids – intravenous	Often fentanyl in the first instance (short- acting), intravenous oxycodone or morphine (especially patients with patient-controlled analgesia). With aperient, with or without antiemetics (not PBS listed for this indication) to counter the side effects of systemic opioids Used for any of the surgery types (except where epidural is preferred) unless patient has a contraindication to opioids.	Up to 80%	~72 hours ^b	Systemic opioids (oral)
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 patients receiving catheter delivery. Open abdominal procedures cited as example where continuous block may be used as alternative. ^a	All neuraxial: 2.5–10%	~72 hours ^c	Systemic opioids (intravenous 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 ^d	

Table 5 List of comparators

Abbreviations: MBS = Medicare Benefits Schedule; PBS = Pharmaceutical Benefits Scheme

Notes: **a** = Italics sentences were added by the applicant in Table 12 of the PICO confirmation and referred to applicant's examples or wording in the PICO document

b = Systemic opioids (intravenous): up to 7 days, depending on patients' surgery, injuries and ability to be treated by other modalities **c** = Epidural block (continuous): up to maximum of 5–7 days with specific supervision for major thoracic or abdominal surgery in specialist centres

d = Spinal block: maximum 3–4 hours with fentanyl, 12–24 hours if subarachnoid morphine is used

Source: DCAR Table 4. Adapted from Ratified PICO Confirmation Table 12; application 1741; per cent estimated values provided by the applicant in pre-PASC teleconference.

The main comparator, confirmed by the ratified PICO Confirmation, which was expected to be replaced, was single-injection nerve block (MBS item 22041, Table 6), associated or not with systemic opioids. According to the applicant, no local anaesthetic agents used for a single-injection nerve block can consistently last beyond 12 hours. MBS item 22041 can only be claimed in conjunction with the anaesthesia item used for the surgical procedure.

Table 6 Single-injection nerve block: MBS item 22041

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 22041

Perioperative introduction of a plexus or nerve block proximal to the lower leg or forearm for post operative pain management (2 basic units).

(See para TN.10.17 of explanatory notes to this Category)

Fee: \$43.60 **Benefit:** 75% = \$32.70 85% = \$37.10

Note: listed since 1 November 2019. 75% benefit is payable for treatment of hospital inpatients; 85% to all other services Source: DCAR Table 5

9. Summary of public consultation input

Consultation input was welcomed from two (2) professional organisations, Sunshine Coast Health and Hospital Services (SCHHS) and Private Healthcare Australia, and six (6) individuals, all of whom were medical specialists.

The consultation feedback received was largely supportive of public funding for continuous nerve blockade using a catheter technique.

Benefits:

- Superior, ongoing and consistent analgesia for patients
- Reduced opioid use
- Equity of access to the benefits of the intervention
- Avoidance of motor and excessive blockade compared to regional analgesia
- Enhanced recovery and early mobilisation of patients
- Reduced length of stay in hospital
- Reduced chronic pain and phantom pain development
- Reduced post-traumatic stress disorder (PTSD) from trauma

Disadvantages

- Additional staff training requirements
- Changes to service delivery in hospitals unfamiliar with the service
- Potential for severe, uncontrolled pain should the system fail
- Increased risk of adverse events including haematoma at insertion site and intravascular infusion of local anaesthetic.
- Increase in costs to the MBS and other payers

Other feedback

The difference in techniques regarding continuous versus top up in catheters was raised, 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.

One respondent stated this technique is not a significant change from current practice, and inferred there is no notable benefit.

10. Characteristics of the evidence base

A systematic search was conducted to address the following SR question: What is the safety, effectiveness and cost-effectiveness of continuous peripheral nerve block versus single-injection nerve block, neuraxial nerve block or systemic opioids in patients undergoing limb or trunk surgery associated with moderate to severe postoperative pain expected to last 12 hours or longer?

The medical literature was searched on 14 August 2023 (and updated on 12 October 2023) to identify relevant randomised controlled trials (RCTs) and SRs. Searches were conducted in 5 databases (Ovid MEDLINE, EMBASE, Cochrane Library, EconLit (EBSCO), The International Network of Agencies for Health Technology Assessment (INAHTA) health technology assessment [HTA] database). These searches retrieved 2,127 records, which included 17 duplicates (the majority of duplicates were removed in the Ovid platform), leaving 2,110 records that were screened by title and abstract (see PRISMA [preferred reporting items for systematic reviews and meta-analyses] chart,). A total of 128 records were then reviewed as full text. A total of 12 RCTs (9 on knee surgery, 3 on trauma) and 9 SRs met the inclusion criteria for assessing the safety and effectiveness of continuous nerve block compared to single-injection nerve block, neuraxial nerve block (epidural) and systemic opioids (intravenous).

Due to applicability issues of the SRs, RCTs on orthopaedic knee surgeries were used to inform the clinical and economic sections. Orthopaedic knee surgery was chosen as the exemplar case because it provided the strongest amount of evidence that aligned with the PICO criteria. Due to the broad range of indications within the overall eligible population it was necessary to prioritise an exemplar case for a detailed assessment of safety, effectiveness and cost effectiveness. Knee replacement surgery is likely to represent a high-value use of peripheral nerve block, as patients undergoing these operations are at high risk of postoperative long-term opioid use due to pre-existing chronic pain associated with this surgical indication. Moreover, these operations are a common type of procedure in Australian private hospitals. In 2021–2022, gonarthrosis (International Classification of Diseases, 10th Revision, Australian Modification [ICD-10-AM] code M17) was the most common principal diagnosis among overnight acute separations in private hospitals and knee replacement—minor complexity (Australian Refined Diagnosis Replated Group [AR-DRG] I04B) was the most common AR-DRG.⁵ 6

For other surgical locations (cardiothoracic, abdominal, shoulders, hips, feet/ankles), SRs were used to report on the clinical effectiveness and safety of continuous nerve block (cNB) after limb (excluding knee) or trunk surgery associated with moderate or severe pain. No SR evidence on trauma patients was retrieved.

The studies used for the clinical evaluation are listed in Table 7. Three RCTs (n = 22, 44 and 88) compared the postoperative analgesic effect of continuous and single-injection nerve block (SNB) in patients who underwent total knee arthroplasty (TKA).^{7 8 9} Two RCTs compared the postoperative analgesic effect of continuous nerve block to epidural block in patients who

⁶ Australian Institute of Health and Welfare. 2023. Admitted patient care 2021-22 5 What services were provided. Available at: <u>https://www.aihw.gov.au/reports-data/myhospitals/sectors/admitted-patients</u>

⁵ Australian Institute of Health and Welfare. 2023. Admitted patient care 2021-22 4 Why did people receive care. Available at: <u>https://www.aihw.gov.au/reports-data/myhospitals/sectors/admitted-patients</u>

⁷ Hirst, G. C., Lang, S. A., Dust, W. N., Cassidy, J. D. & Yip, R. W. 1996. Femoral nerve block. Single injection versus continuous infusion for total knee arthroplasty. Reg Anesth, 21, 292-7.

⁸ Kim, M. K., Moon, H. Y., Ryu, C. G., Kang, H., Lee, H. J. & Shin, H. Y. 2019. The analgesic efficacy of the continuous adductor canal block compared to continuous intravenous fentanyl infusion with a single-shot adductor canal block in total knee arthroplasty: a randomized controlled trial. Korean J Pain, 32, 30-38.

⁹ Park, C. K., Cho, C. K., Lee, G. G. & Lee, J. H. 2010. Optimizing dose infusion of 0.125% bupivacaine for continuous femoral nerve block after total knee replacement. Korean J Anesthesiol, 58, 468-76.

underwent TKA (n = 50 and 100).¹⁰ ¹¹ Four RCTs compared the postoperative analgesic effect of continuous nerve block to intravenous opioids in patients who underwent knee-related operative procedures, either TKA (n = 40, 46 and 280 ¹² ¹³ ¹⁴ or anterior cruciate ligament reconstruction (n = 104)¹⁵.

The quality of the RCTs were assessed using the Cochrane Risk of Bias Tool for Randomised Trials (RoB2).¹⁶ Seven of the RCTs for knee surgeries were evaluated as having some concerns , and 2 as having a high RoB owing to concerns with blinding of participants/personnel (domain 2) (see Table 7). AMSTAR 2 (Assessing the Methodological Quality of Systematic Reviews 2) was used for the SRs.¹⁷ The overall quality of the SRs varied, with 5 assessed as being critically low quality, 3 assessed as low quality and only one being high quality.

References	n	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
Comparator: single-inj	ection ne	erve block ^a				
Hirst et al (1996)	22	RCT/72h	Some concerns	TKA	Pain scores Rescue analgesia Block-related AEs	Yes
Park et al (2010)	88	RCT/POD2	High	TKA	Pain scores Rescue analgesia Block re-attempt and -related AEs	Yes
Kim et al (2019)	44	RCT/POD4	Some concerns	ТКА	Pain scores Rescue analgesia Block-related AEs	Yes
Comparator: systemic	opioids ^b	-		•		
Dodds et al (1995)	104	RCT/48h	High	Anterior cruciate ligament reconstruction	Pain scores Rescue analgesia Block re-attempt and -related AEs	Scenario analysis only
Yu et al (2018)	46	RCT/48h	Some concerns	TKA	Pain scores	Scenario analysis only

Table 7 Key features of the included evidence for knee surgery

¹⁰ Sreenath, M. K., A., K.; Manchala, K.; Anusha, D., V., B.; Reddy, B., V. 2022. Continuous epidural analgesia versus continuous femoral nerve block in management of post-operative pain in patients undergoing unilateral total knee arthroplasty: An open labelled randomized controlled trial. European Journal of Molecular & Clinical Medicine, 9(1), 711-718.

¹¹Yacout, A. G. & Elhoshy, H. S. 2023. Continuous femoral nerve block enhances outcome of spinal anaesthesia in preventing perioperative cardiac complications in patients with cardiac risk. Egyptian Journal of Anaesthesia, 39, 177-184.

¹² Lee, J. J., Choi, S. S., Lee, M. K., Lim, B. G. & Hur, W. 2012. Effect of continuous psoas compartment block and intravenous patient controlled analgesia on postoperative pain control after total knee arthroplasty. Korean J Anesthesiol, 62, 47-51.

¹³ Peng, L., Ren, L., Qin, P., Chen, J., Feng, P., Lin, H. & Su, M. 2014. Continuous Femoral Nerve Block versus Intravenous Patient Controlled Analgesia for Knee Mobility and Long-Term Pain in Patients Receiving Total Knee Replacement: A Randomized Controlled Trial. Evid Based Complement Alternat Med, 2014, 569107.

¹⁴ Yu, Y. L., Cao, D. H., Chen, B., Yang, Z. H. & You, K. Z. 2018. Continuous femoral nerve block and patient-controlled intravenous postoperative analgesia on Th1/Th2 in patients undergoing total knee arthroplasty. J Biol Regul Homeost Agents, 32, 641-647.

¹⁵ Dodds, R. D. McMeniman, P.J. Krippner, R. Myers, P. T. 1995. Comparison of intravenous pethidine infusion with '3 in 1' lumbar plexus block after anterior cruciate ligament reconstruction. The Knee, 2(1), 43-46.

¹⁶ Sterne, J. A. C., Savović, J., Page, M. J., Elbers, R. G., Blencowe, N. S., Boutron, I., Cates, C. J., Cheng, H. Y., Corbett, M. S., Eldridge, S. M., Emberson, J. R., Hernán, M. A., Hopewell, S., Hróbjartsson, A., Junqueira, D. R., Jüni, P., Kirkham, J. J., Lasserson, T., Li, T., McAleenan, A., Reeves, B. C., Shepperd, S., Shrier, I., Stewart, L. A., Tilling, K., White, I. R., Whiting, P. F. & Higgins, J. P. T. 2019. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ, 366, I4898.

¹⁷ Shea, B. J., Reeves, B. C., Wells, G., Thuku, M., Hamel, C., Moran, J., Moher, D., Tugwell, P., Welch, V., Kristjansson, E. & Henry, D. A. 2017. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ, 358, j4008.

References	n	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
Lee et al (2012)	40	RCT/48h	Some concerns	TKA	Pain scores Rescue analgesia Block-related AEs LOS	Scenario analysis only
Peng et al (2014)	280	RCT/12months	Some concerns ^c	TKA	Pain scores Rescue analgesia Block-related AEs CPOP	Scenario analysis only
Comparator: neuraxial block ^d						
Sreenath et al (2022)	100	RCT/POD14	Some concerns	TKA	Pain scores Rescue analgesia	Scenario analysis only
Yacout and Elhoshy (2023)	50	RCT/48h	Some concerns	TKA	Pain scores Rescue analgesia	Scenario analysis only

Abbreviations: AE = adverse event; CPOP = chronic postoperative pain; IV = intravenous; LOS = length of stay; n = number of patients; NSAID = non-steroidal anti-inflammatory drug; PCA = patient-controlled analgesia; POD = postoperative day; RCT = randomised controlled trial; TKA = total knee arthroplasty

Notes: a = These studies used a continuous nerve block associated with a patient-controlled analgesia pump filled with a local anaesthetic or an opioid with or without NSAID. A patient-controlled analgesia pump was also used in the single-injection group and was filled with an opioid, with or without NSAID

b = The intervention and the comparators varied. The effect of continuous nerve block was either assessed alone or in association with a patient-controlled analgesia pump, filled with a local anaesthetic (Yu et al [2018] and Peng et al [2014]) or a combination of opioids and NSAID (Lee et al [2012]). Intravenous opioid was injected either alone (Dodds et al [1995]), in association with NSAID (Lee et al [2012]), or with NSAID and steroid (Peng et al [2014])

c = Peng et al (2014) was rated as having a high RoB for analgesic use; other outcomes were rated as having some concerns. d = Epidural blocks consisted of local anaesthetic with or without opioid. Patients in both the intervention and the comparator groups received a patient-controlled analgesia pump filled with opioids

Source: DCAR Table 6

11. Comparative safety

Exemplar case: knee surgery

Continuous nerve block vs single-injection nerve block

Limited evidence was available to evaluate safety when comparing continuous nerve block to single-injection nerve block. In the included RCTs, no evidence was reported on deaths/mortality or local anaesthesia toxicities. Zero events of block-related complications or catheter AEs were reported. For complications or grade ≥3 AEs, 2 RCTs reported nausea and vomiting; however, no statistically significant difference between continuous nerve block and single-injection nerve block was reported at 48 hours. For nausea and vomiting, the overall GRADE (Grade of Recommendations Assessment, Development and Evaluation) certainty of evidence was assessed to be very low.

A results comparison between the exemplar case and the other surgical locations is presented in Table 8.

Outcomes	Exemplar case knee surgery (RoB, GRADE)	Other surgical locations: foot and ankle, hips, abdomen, cardiothorax and shoulders (Overall quality °)
Block-related complications	k=1 (some concerns, GRADE low) No AEs	k=3 (SR: critically low and low, RCT: some concerns) No major AEs ^a Minor AEs ^b
Catheter AEs	k=1 (some concerns, GRADE NA) No infection	k=2 (SR: critically low, RCT: some concerns) No infections
Local anaesthesia toxicity	NR	NR
Death/mortality	NR	k=1 (RCT: some concerns) No deaths

Table 8	Continuous nerve block vs single-injection nerve bloc	ck: summary of the main outcomes
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Abbreviations: AE = adverse event; GRADE = Grading of Recommendations Assessment, Development and Evaluation; k = number of studies; NA = not applicable; NR = not reported; RCT = randomised controlled trial; RoB = risk of bias; SR = systematic review Notes: a = Major block-related AEs, including procedure-related or infusion system-related AEs such as neuropathic symptoms, adverse

drug reactions or accidental fall were reported.

b = Minor block-related AEs included motor block (defined as difficulty in finger flexion or extension at 12 h after shoulder surgery), drug leakage, catheter dislodgment or blockade, and pump malfunction.

 \mathbf{c} = Overall quality scores were appraised using the AMSTAR-2 critical appraisal tool.

Source: DCAR Table 7

Continuous nerve block vs systemic opioids

Limited evidence was available to evaluate safety when comparing continuous nerve block to systemic opioids. In the included RCTs, no evidence was reported on deaths/mortality, or local anaesthesia toxicities. Zero events of block-related complications or catheter AEs were reported. For complications or grade \geq 3 AEs, 3 RCTs reported nausea and vomiting, with a statistically significant difference favouring continuous nerve block reported at 48 to 72 hours. For nausea and vomiting, the overall GRADE certainty of evidence was assessed to be low.

A results comparison between the exemplar case and the other surgical locations is presented in Table 9.

Outcomes	Exemplar case knee surgery (RoB, GRADE)	Other surgical locations: foot and ankle, hips, abdomen, cardiothorax and shoulders (Overall quality ^b)
Block-related complications	k=2 (some concerns, GRADE moderate) No AEs	k=1 (RCT: low) Minor AEs ^a
Catheter AEs	k=1 (some concerns, GRADE NA) No infection	k=1 (RCT: low) No infection
Local anaesthesia toxicity	NR	k=1 (RCT: NA) No toxicity
Death/mortality	NR	k=1 (RCT: low) No statistically significant difference

 Table 9
 Continuous nerve block vs systemic opioids: summary of the main outcome

Abbreviations: AE = adverse event; GRADE = Grading of Recommendations Assessment, Development and Evaluation; k = number of studies; NA = not applicable; NR = not reported; RCT = randomised controlled trial; RoB = risk of bias

Notes: **a** = Minor block-related AEs included drug leakage, vascular puncture and intra-epineural injection without neuropathy. There was no peripheral nerve injury or compartment syndrome.

b = Overall quality scores were appraised using the AMSTAR-2 critical appraisal tool. Source: DCAR Table 8

Continuous nerve block vs neuraxial nerve block

Limited evidence was available to evaluate safety when comparing continuous nerve block to neuraxial nerve block. In the included RCTs, no evidence was reported on deaths/mortality, local anaesthesia toxicities, block-related complications, or catheter AEs, For complications or grade ≥3 AEs, 1 RCT reported nausea and vomiting; however, no statistically significant difference between continuous nerve block and neuraxial nerve block was reported at 72 hours. For nausea and vomiting, the overall GRADE certainty of evidence was assessed to be very low.

A results comparison between the exemplar case and the other surgical locations is presented in Table 10.

Outcomes	Exemplar case knee surgery (RoB, GRADE)	Other surgical locations: foot and ankle, hip abdomen, cardiothorax and shoulder (Overall quality ^b)		
Block-related complications	NR	k=3 (SR: high, critically low and low) No AEs with continuous nerve block ^a		
Catheter AEs	NR	NR		
Local anaesthesia toxicity	NR	NR		
Death/mortality	NR	NR		

Table 10 Continuous nerve block vs neuraxial block: summary of the main outcomes

Abbreviations: AE = adverse event; GRADE = Grading of Recommendations Assessment, Development and Evaluation; k = number of studies; NR = not reported; RoB = risk of bias; SR = systematic review

Notes: a = One SR reported abdominal wall haematoma without certainty of the cause and another reported only catheter dislocation or removal with the neuraxial procedure.

b = Overall quality scores were appraised using the AMSTAR-2 critical appraisal tool. Source: DCAR Table 9

12. Comparative effectiveness

Exemplar case: knee surgery

Continuous nerve block vs single-injection nerve block

Three RCTs were included to compare continuous nerve block to single-injection nerve block. Two were evaluated to have some concern of bias and one was evaluated to have a high RoB. All studies were assessed as having some concerns for selective reporting.

Statistically significant differences were reported in favour of continuous nerve block for patientreported postoperative pain scores at 48 hours. No statistically significant differences were reported between continuous nerve block and single-injection nerve block for patient satisfaction, supplementary analgesia, opioid consumption and block-reattempt/block failure between 48 and 72 hours. The overall GRADE certainty of evidence for patient-reported postoperative pain scores, opioid consumption for breakthrough pain and block reattempt/block failure was assessed to be very low.

In the included RCTs, time to first mobilisation post-surgery, rate of chronic postoperative pain, chest infection/pneumonia, health-related quality of life, hospital length of stay and rehospitalisation due to pain were not reported.

A results comparison between the exemplar case and the other surgical locations is presented in Table 11.

Table 11	Continuous nerve	block vs sinale-in	iection nerve block:	summary of the main	n outcomes
		blook vo olligie il		Summary of the man	1 outcomes

Outcomes	Exemplar case knee surgery (RoB, GRADE)	Other surgical locations: foot and ankle, hips, abdomen, cardiothorax and shoulders (Overall quality ^a)
Effectiveness	·	·
Patient-reported postoperative pain score	k=3 (some concerns, GRADE very low) Statistically significant difference in favour of continuous nerve block	k=2 (SR: low, RCT: some concerns) Mixed results Statistically significant difference in favour of continuous nerve block or no difference
Incidence of supplementary analgesia use	k=2 (high RoB and some concerns, GRADE NA) No statistically significant difference	k=3 (SR: critically low, RCT: some concerns) No statistically significant difference
Opioid consumption for breakthrough pain	k=3 (high RoB and some concerns, GRADE very low) No statistically significant difference	k=5 (SRs: low, critically low, RCTs: some concerns) Mixed results Statistically significant difference in favour of continuous nerve block or no difference
Health-related quality of life	NR	NR
Healthcare system	·	
Block re-attempt	k=2 (high RoB and some concerns, GRADE very low) No statistically significant difference	k=1 (RCT: some concerns) No significant difference
Hospital length of stay	NR	k=2 (SR: low, RCT: some concerns) Mixed results Statistically significant difference in favour of continuous nerve block or no difference

Abbreviations: AE = adverse event; k = number of studies; NR = not reported; RCT = randomised controlled trial; RoB = risk of bias; SR = systematic review

Notes: **a** = Overall quality scores were appraised using the AMSTAR-2 critical appraisal tool. Source: DCAR Table 10

Continuous nerve block vs systemic opioids

Four RCTs were included to compare continuous nerve block with systemic opioids. Three were evaluated to have some concerns of bias and one was evaluated to have a high RoB. All studies were assessed as having some concerns for measurement of the outcome and selective reporting.

One RCT reported opioid consumption for breakthrough pain, with a statistically significant difference in favour of continuous nerve block reported at 72 hours. One RCT reported the rate of chronic postoperative pain, with a significantly reduced incidence of chronic postoperative pain observed in the continuous nerve block group compared to the systemic opioid group at both 3 months and 6 months. Two RCTs reported block re-attempt/block failure, with a statistically significant difference in favour of systemic opioids reported at 48 to 72 hours. No statistically significant differences were reported between continuous nerve block and systemic opioids for patient-reported postoperative pain scores, patient satisfaction, supplementary analgesia or hospital length of stay. The overall GRADE certainty of evidence for patient-reported postoperative pain scores, opioid consumption for breakthrough pain and block-reattempt/block failure was assessed to be very low.

In the included RCTs, time to first mobilisation post-surgery, chest infection/pneumonia, healthrelated quality of life and rehospitalisation due to pain were not reported. A results comparison between the exemplar case and the other surgical locations is presented in Table 12.

Outcomes	Exemplar case knee surgery (RoB, GRADE)	Other surgical locations: foot and ankle, hips, abdomen, cardiothorax and shoulders (Overall quality ^a)
Effectiveness		
Patient-reported postoperative pain score	k=4 (high RoB and some concerns, GRADE very low) No statistically significant difference at 48h to 168h	 k=2 (SR: low, RCT: some concerns) Mixed results Statistically significant difference in favour of continuous nerve block or no difference
Incidence of supplementary analgesia use	k=2 (high RoB and some concerns, GRADE NA) No statistically significant difference	k=2 (SRs: critically low) No statistically significant difference
Opioid consumption for breakthrough pain	k=1 (high RoB, GRADE very low) Statistically significant difference in favour of continuous nerve block	k=5 (SRs: low and critically low, RCTs: some concerns) Mixed results Statistically significant difference in favour of continuous nerve block or no difference
Health-related quality of life	NR	NR
Healthcare system		
Block re-attempt	k=2 (high RoB and some concerns, GRADE very low) A statistically significant difference in favour of systemic opioids at 48h to 72h	k=1 (RCT: low) Continuous nerve block: 5.5% Systemic opioids 0.0%, no statiscal test performed
Hospital length of stay	k=1 (RoB some concerns, GRADE NA) No statistically significant difference	k=2 (SR: high, RCT: NA) Mixed results A statistically significant difference in favour of continuous nerve block or no difference

Table 12 Continuous nerve block vs systemic opioids: summary of the main outcomes

Abbreviations: AE = adverse event; GRADE = Grading of Recommendations Assessment, Development and Evaluation; h = hours; k = number of studies; NA = not applicable; NR = not reported; RCT = randomised controlled trial; ROB = risk of bias; SR = systematic review Notes: a = Overall quality scores were appraised using the AMSTAR-2 critical appraisal tool. Source: DCAR Table 11

Continuous nerve block vs neuraxial nerve block

Two RCTs were included to compare continuous nerve block with neuraxial nerve block. Both were assessed as having a RoB of some concerns for measurement of the outcome, the randomisation process and selective reporting.

Two RCTs reported the use of rescue analgesia, with a statistically significant difference in favour of continuous nerve block reported at 48 to 72 hours. One RCT reported opioid consumption for breakthrough pain, with a statistically significant difference in favour of continuous nerve block reported at 48 hours. One RCT reported patient satisfaction, with patients in the continuous nerve block group more significantly satisfied relative to those in the neuraxial nerve block group at 48 hours. No statistically significant differences were reported between continuous nerve block and neuraxial nerve block for patient-reported postoperative pain scores. The overall GRADE certainty of evidence for patient-reported postoperative pain scores and opioid consumption was assessed to be very low.

In the included RCTs, time to first mobilisation post-surgery, rate of chronic postoperative pain, chest infection/pneumonia, health-related quality of life, block-reattempt/block failure, hospital length of stay and rehospitalisation due to pain were not reported.

A results comparison between the exemplar case and the other surgical locations is presented in Table 13.

Outcomes	Exemplar case knee surgery (RoB, GRADE)	Other surgical locations: foot and ankle, hips, abdomen, cardiothorax and shoulders (Overall quality b)
Effectiveness		quality ;
Patient-reported postoperative pain scores	k=2 (some concerns, GRADE very low) No statistically significant difference at 48h to 72h	k=3 (SRs: low and critically low) Mixed results No difference or statistically significant difference in favour of neuraxial block ^a
Incidence of supplementary analgesia use	k=2 (some concerns, GRADE NA) Statistically significant difference in favour of continuous nerve block	 k=3 (SRs: critically low and low) No difference (k=2) Statistically significant difference in favour of continuous nerve block according to follow-up time (k=1 at 72h), or patient population (children, k=1).
Opioid consumption for breakthrough pain	k=1 (RoB: some concerns, GRADE very low) Statistically significant difference in favour of continuous nerve block	k=3 (SRs: critically low and low) Mixed results No difference (k=2) or statistically significant difference in favour of continuous nerve block (k=1)
Health-related quality of life	NR	NR
Healthcare system		
Block re-attempt	NR	k=1 (SR: low) Favours continuous nerve block (0 event vs neuraxial block 10-26%)
Hospital length of stay	NR	k=3 (SRs: critically low, low and high) No statistically significant difference

 Table 13
 Continuous nerve block vs neuraxial block: summary of the main outcomes

Abbreviations: GRADE = Grading of Recommendations Assessment, Development and Evaluation; k = number of studies; NR = not reported; RoB = risk of bias; SR = systematic review

Notes: **a** = Statistically significant results in favour of neuraxial block—when postoperative pain was assessed in motion, or according to surgical types, specific continuous nerve blocks or regular NSAID use—were reported in some SRs but not confirmed by other SRs assessing the same criteria.

b = Overall quality scores were appraised using the AMSTAR-2 critical appraisal tool. Source: DCAR Table 12

Clinical claim

The clinical claim of **superior effectiveness**, based on **uncertain** evidence, and **non-inferior safety** was supported for continuous peripheral nerve block relative to a single-injection nerve block in patients undergoing knee surgery associated with moderate to severe postoperative pain expected to last 12 hours or longer.

The evidence suggests that continuous peripheral nerve block has **superior effectiveness** (based on **uncertain** evidence) and **non-inferior safety** relative to systemic opioids in patients undergoing knee surgery associated with moderate to severe postoperative pain expected to last 12 hours or longer.

There was insufficient evidence to draw conclusions on the relative effectiveness and safety of continuous peripheral nerve block relative to a neuraxial nerve block in patients undergoing knee surgery associated with moderate to severe postoperative pain expected to last 12 hours or longer.

13. Economic evaluation

Methods

An economic evaluation in the form of a cost-effectiveness analysis (CEA) was conducted to determine the value of continuous nerve block for the treatment of postoperative pain in adult patients. A CEA was selected based on the claim of superior clinical effectiveness of continuous nerve block when compared to a single-injection nerve block presented in the ratified PICO (based on the relative duration of analgesia a continuous block can provide). The clinical assessment found continuous nerve block to be associated with statistically and clinically significant improvements in pain relative to single-injection nerve block at 48 hours post-surgery and clinically significant reductions in opioid consumption.

In its review of application 1308 (Local anaesthetic nerve blockade for post-surgical analgesia), MSAC expressed concern at the lack of patient-centred outcomes in the economic modelling and noted that the inclusion of information about the impact of nerve blocks upon pain in an economic model was key to its decision-making. The model presented in this department-contracted assessment report (DCAR) estimated the cost per one-unit improvement in pain (measured via VAS) as an incremental cost-effectiveness ratio (ICER). No evidence on the impact of continuous nerve block on broader aspects of quality of life, nor on reduced opioid dependence, was identified. Translation into a cost-utility analysis (CUA) was considered infeasible.

Due to the large variety of surgical procedures where both continuous and single-injection nerve block can be applied, only orthopaedic knee surgeries—which are common elective orthopaedic procedures¹⁸—were considered for the base case of the economic evaluation.

A review of the existing economic literature on the topic identified existing cost comparisons (k = 5); however, no existing CEAs or CUAs were identified. A de novo decision tree model—based on the Australian treatment algorithms provided in the ratified PICO—was developed to estimate the ICER. The decision tree structure (depicted visually in the main body of the report) included probabilities relating to the need for rescue opioids, risk of catheter complications and/or failure (or risk of injection failure for single-injection nerve block), and patient experience of nausea or vomiting. An overview of key model characteristics is detailed in Table 14.

¹⁸ Blom, A. W., Donovan, R. L., Beswick, A. D., Whitehouse, M. R. & Kunutsor, S. K. 2021. Common elective orthopaedic procedures and their clinical effectiveness: umbrella review of level 1 evidence. BMJ, 374, n1511.

Perspective	Australian healthcare system
Population	Adults (≥18 years) undergoing orthopaedic knee surgery
Intervention	Continuous nerve block for postoperative pain
Comparator	Single-injection nerve block
Type(s) of analysis	Cost-effectiveness analysis
Outcome	Improvement in postoperative pain
Time horizon	5 days
Computational method	Decision tree
Generation of base case	Modelled (i.e. informed by meta-analyses conducted in the clinical assessment)
Discount rate	Not applied due to short time horizon
Sensitivity analysis	Deterministic sensitivity analysis to explore uncertainly in cost and health outcomes
Software	TreeAge Pro

Table 14 Summary of the economic evaluation

Source: DCAR Table 13

Results

The incremental cost and incremental effectiveness of continuous nerve block and singleinjection nerve block performed in the inpatient setting, are detailed in Table 15. Compared with single-injection nerve block, the proposed intervention is associated with greater costs and improved effectiveness (i.e. a decrease in pain at 48 hours after surgery). An ICER of \$114.35 per one-unit improvement in post-surgical pain was estimated.

Table 15 Results of the economic evaluation

Parameter	Continuous nerve block	Single-injection nerve block	Incremental
Costs	\$4,556.34	\$4,401.97	\$154.37
Pain ^a	7.316	5.966	1.350
Incremental cost per one-unit improvement in pain			\$114.35

Notes: a: measured on a scale 0-10, with 0 indicating the worst pain and 10 indicating no pain. Pain was measured at 48 hours after surgery.

Source: DCAR Table 14

The summary of disaggregated cost outcomes (Table 16) showed that the main drivers of the increased cost related to associated equipment (i.e. the catheter infusion kit) and hospital/medical services (i.e. catheter placement; additional anaesthetist consult prior to discharge). Incremental effectiveness outcomes were driven solely by differences in patient reported pain at 48 hours after surgery.

Type of resource	Cost for continuous nerve block	Cost for single- injection nerve block	Incremental cost
Associated equipment: catheter infusion kits, needles, syringes	\$80.00	\$1.30	\$78.70
Medicines: anaesthetic (ropivacaine/bupivacaine) and non-opioid analgesia (paracetamol/ibuprofen)	\$37.42	\$27.24	\$10.18
Medical services: nerve block placement, ultrasound guidance, anaesthesia consultation (including copayments)	\$663.56	\$474.14	\$189.42
Hospital accommodation	\$3,739.96	\$3,878.78	-\$138.82
Opioid consumption for breakthrough pain	\$2.25	\$2.98	-\$0.73
Block failure/re-attempt	\$28.65	\$11.25	\$17.41
Antiemetic use for nausea/vomiting	\$4.49	\$6.29	-\$1.80
Total	\$4,556.34	\$4,401.97	\$154.37

Table 16 Summary of disaggregated cost outcomes at the resource-type level and for the base case analysis

Source: DCAR Table 15

Uncertainty analysis

A deterministic one-way sensitivity analysis was undertaken to investigate the impact of parameter uncertainty on disaggregated outcomes. Uncertainty ranges were included for the following input parameters: probability of nausea and vomiting, block-related complications or need for rescue analgesia; effectiveness payoff (i.e. pain; inverse VAS); resource utilisation parameters of length of hospital stay and average number of opioid doses required for rescue analgesia; and additional out of pocket costs above the MBS fee for the proposed item and for the comparator.

Scenario analyses were undertaken to investigate alternative modes of delivery (i.e. inpatient vs ambulatory continuous nerve block) and to compare the intervention to the secondary comparators (i.e. neuraxial block and intravenous opioids).

Key drivers of the model are summarised in Table 17.

Description	Method/Value	Impact
Effectiveness payoff	Postoperative pain experienced at 48 hours following knee surgery measured on a 0–10 VAS. The inverse of the reported VAS scores, for continuous nerve block and single-injection nerve block, were used as model inputs for the CEA. These inputs were each associated with a 95% CI for sensitivity analysis.	High, direction of effect (i.e. if favours intervention or comparator) is uncertain. Note: clinical assessment found a significant and clinically meaningful difference in post-surgical pain at 48 hours in favour of continuous nerve block.
Relative duration of hospital stay	Length of hospital stay inputs were informed by an existing SR, which reported a non-significant difference after knee surgery with continuous or single-injection nerve block. These inputs were each associated with a 95% CI for sensitivity analysis.	High impact on incremental costs, direction of effect (i.e. if favours intervention or comparator) is uncertain.
Relative out-of- pocket costs for the nerve block procedure	Out-of-pocket costs (above the MBS fee) were included for both continuous and single-injection nerve blocks. In the absence of data on out-of-pocket costs for item 22041, these inputs were set equal across arms in the base case. They were varied, individually, in sensitivity analysis using an arbitrary ±20%.	High impact on incremental costs. Impact dependent on relative value of out-of- pocket costs across arms. Lack of data for MBS item 22041 inhibited further exploration of this issue.
Setting for continuous nerve block (inpatient vs ambulatory) ^a	Scenario analysis using alternate cost inputs to capture the alternate practice for patients who can be discharged with the catheter in place. No change to the clinical evidence used.	High, this scenario favours the comparator. Use of alternative cost assumptions increased incremental costs. Note: separate clinical evidence for the ambulatory setting was not available.

Table 17 Key drivers of the model (continuous nerve block versus single-injection nerve block)

Abbreviations: CEA = cost-effectiveness analysis; CI = confidence interval

Notes: **a** = Number of ambulatory patients as a proportion of likely use remains unknown (noted in the ratified PICO)—a weighted average could not be reliably defined, therefore an alternate scenario was considered.

Source: DCAR Table 16

The effectiveness payoff was found to be a key driver of the economic results. Nevertheless, the evidence suggested that continuous nerve block has a statistically and clinically significant positive effect on post-surgical pain at 48 hours relative to single-injection nerve block. Based on the input variables for post-surgical pain, there was high certainty that continuous nerve block was associated with a positive incremental effect.

Differences in opioid/supplementary analgesia consumption had minimal impact on the incremental cost. No outcome data on opioid dependence were identified; therefore, any related economic issues could not be assessed.

Use of a disposable elastomeric infusion pump increases the incremental cost; however, a separate clinical assessment of the safety/effectiveness was not possible, so it was unknown whether this increased incremental cost was also associated with improved incremental benefits.

The results of key univariate sensitivity analyses and scenario analyses are summarised in Table 18.

Table 18 Key sensitivity and scenario analyses

Analyses	Incremental cost	Incremental improvement in pain	ICERª
Base case	\$154.37	1.35	\$114.35
Effectiveness payoffs (for DSA))		
Pain (0 to 10 scale) ^b associated with continuous nerve block (95% CI: 6.81 to 7.83)	\$154.37	0.84 1.86	\$183.99 \$82.91
Pain (0 to 10 scale) ^b associated with single-injection nerve block (95% CI: 5.69 to 6.25)	\$154.37	1.63 1.07	\$94.65 \$144.54
Two-way sensitivity analysis on pain: cNB: 6.81; sNB: 5.69 cNB: 6.81; sNB: 6.25 cNB: 7.83; sNB: 5.69	\$154.37	1.12 0.56 2.14	\$137.83 \$277.15 \$72.04
cNB: 7.83; sNB: 6.25		1.58	\$97.70
Resource use inputs (length of	hospital stay)	·	
Duration of hospital stay, continuous nerve block (95% Cl: 3.54 to 3.68)	\$79.78 \$228.96	1.35	\$59.10 \$169.60
Duration of hospital stay, single- injection nerve block (95% CI: 3.68 to 3.81)	\$225.86 \$82.89	1.35	\$167.30 \$61.40
Two-way sensitivity analysis on length of hospital stay: cNB: 3.54; sNB: 3.68 cNB: 3.54; sNB: 3.81 cNB: 3.68; sNB: 3.68 cNB: 3.68; sNB: 3.81	\$151.26 \$8.30 \$300.45 \$157.48	1.35	\$112.05 \$6.14 \$222.55 \$116.65
Comparator (base case: single-	injection nerve block)		
Continuous epidural infusion	-\$90.15	0.44	cNB dominant
Intravenous opioids	\$598.19	0.34	\$1,775.04
Setting of continuous nerve blo	ock (base case: inpatie	nt)	
Discharged with catheter c	\$593.17	1.350	\$439.39

Abbreviations: CI = confidence interval; cNB = continuous nerve block; DSA = deterministic sensitivity analysis; ICER = incremental costeffectiveness ratio; NB = nerve block; sNB = single-injection nerve block

Notes: a = ICER reports the incremental cost per one-unit improvement in pain (on 10-point scale).

b = 10 is no pain, 0 is worst pain imaginable

c = This scenario considers patients discharged with the catheter in place, including costs for elastomeric infusion pump. Source: DCAR Table 17.

14. Financial/budgetary impacts

Anticipated use of the proposed health technology was estimated using a market share approach involving 2 components:

- estimated rate of substitution of current MBS services by the proposed health technology
- estimated potential growth of the market after listing of the proposed health technology.

The primary comparator was single-injection nerve block. Single-injection peripheral nerve blocks are currently reimbursed via MBS item 22041. The financial analysis assumed that a proportion of claims for MBS item 22041 would be substituted by the proposed health technology, should it be listed.

In the ratified PICO, the applicant indicated that some use of the existing single-injection nerve block item may be due to claims for continuous nerve blocks in lieu of a more appropriate item. Nevertheless, no data were available to support estimates of such leakage in practice, and lack of an MBS item may, in fact, be limiting uptake of continuous nerve blocks. Whilst substitution was modelled, the extent to which this anticipated shift reflected a change in claims practices rather than a true shift in clinical practice from single-injection to continuous catheter peripheral nerve blocks was uncertain.

The financial analysis considered that the overall number of MBS claims for peripheral nerve blocks would likely grow should the proposed MBS item be listed. To inform estimates of market growth, data on the overall use of catheters for peripheral nerve blocks were considered. After accounting for continuous nerve blocks that would substitute for existing single-injection nerve block services, the total number of continuous nerve block services—that is, both substituted services and additional MBS services—was derived as a percentage of all peripheral nerve block services.

In year 1 of the financial analysis (financial year [FY] 2024–25), a total of 28,758 continuous catheter peripheral nerve block services was estimated, including 11,329 services anticipated to replace MBS item 22041 claims and 17,429 additional services reflecting a growth in the MBS market of peripheral nerve block services. For the services anticipated to replace MBS item 22041 claims, the value of MBS item 22041 reflected a cost offset for the net financial impact calculations.

Changes in use of other health technologies beyond the substituted single-injection nerve block services were not considered in the base case. Given the reported widespread utilisation of continuous nerve blocks, it was assumed that significant changes in the use and cost of other health technologies would not be expected should the proposed MBS item be listed.

The financial implications to the MBS resulting from the proposed listing of continuous nerve block using a catheter technique are summarised in Table 19.

Parameter	FY 2024–25	FY 2025–26	FY 2026–27	FY 2027–28	FY 2028–29	FY 2029–30	
Estimated use and cost of the proposed health technology							
Number of MBS services for continuous NB (75% benefit: \$81.75)	28,758	30,195	31,705	33,290	34,955	36,703	
Cost to the MBS (with appropriate copayments excluded; \$ million)	2.35	2.47	2.59	2.72	2.86	3.00	
Change in use and cost of other health te	Change in use and cost of other health technologies						
Number of 22041 services (75% benefit: \$32.70)	-11,329	-11,895	-12,490	-13,114	-13,770	-14,459	
Change in cost to the MBS (with appropriate copayments excluded; \$ million)	-0.37	-0.39	-0.41	-0.43	-0.45	-0.47	
Net financial impact to the MBS (\$ million)	1.98	2.08	2.18	2.29	2.41	2.53	

Table 19	Net financial implications	to the MBS of continuous	nerve block using a catheter	r technique
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Abbreviations: FY = financial year; MBS = Medicare Benefits Schedule; NB = nerve block Source: DCAR Table 18

Out-of-pocket costs

The net financial impact was calculated using the 75% benefits of the proposed MBS item and of MBS item 22041. While this accounted for the direct financial impact to the MBS, it did not capture patient out-of-pocket costs. In the ratified PICO, the applicant suggested that actual cost for the service would be approximately \$303.56. This is higher than the proposed fee of \$109.00 (75% benefit: \$81.75), indicating out-of-pocket costs are likely. The difference between the actual cost and the proposed fee in the ratified PICO—based on the value of one RVG unit at the time the PICO was published—was \$198.80/patient. Inflating the estimated service cost by the same indexation rate observed for the proposed item fee between publication of the PICO and this financial analysis (+4.06%) derived an estimated cost of approximately \$315.88 and a difference of \$206.88 between the service cost and the item fee. Including the 25% of the MBS fee not funded through Medicare (\$27.25), this equated to a total gap of \$234.13.

Department of Health and Aged Care data indicated that, of patients who had an MBS item 22031 service in a private setting within Australia in FY 2021–22, 98% had an out-of-pocket cost.¹⁹ According to the Department of Health and Aged Care's Medical Costs Finder website, the typical out-of-pocket cost for each patient was \$204. The current MBS fee for item 22031²⁰ is, similar to the proposed item, costed at 5 basic units per the RVG for anaesthesia services (MBS fee as of 1 November 2023: \$109.00).²¹ This item could therefore be expected to have a similar level of complexity, given RVG item fees are a measure of complexity. Out-of-pocket cost data for MBS item 22041 were not available on the Medical Costs Finder website.

Uncertainties

Sensitivity analyses were included for assumptions relating to the growth rate for peripheral nerve block services, the substitution rate for MBS item 22041, and the overall use of catheters for peripheral nerve blocks. The latter had the largest impact on the anticipated net financial impact of the proposed listing, likely because this input parameter impacted the estimated market growth for MBS-subsidised peripheral nerve block services. Across the deterministic sensitivity analyses conducted, the net financial impact to the MBS was estimated at \$1.41 million to \$2.62 million in year 1 of listing (FY 2024–25; Table 20).

¹⁹ Department of Health and Aged Care. 2023. Medical Costs Finder [Online]. Available at: <u>https://www.health.gov.au/resources/apps-and-tools/medical-costs-finder</u> [Accessed 14 November 2023].

²⁰ MBS item 22031: 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.

²¹ Department of Health and Aged Care. 2023. MBS Online [Online]. Available: <u>http://www.mbsonline.gov.au/</u> [Accessed 14 November 2023].

Scenario	FY	FY	FY	FY	FY	FY		
	2024–25	2025–26	2026–27	2027–28	2028–29	2029–30		
Base case (\$ million)	1.98	2.08	2.18	2.29	2.41	2.53		
One-way deterministic analysis								
Growth rate of peripheral NBs	1.94 to	2.02 to	2.10 to	2.19 to	2.27 to	2.36 to		
5.0% p.a. ±20% (\$ million)	2.02	2.14	2.27	2.40	2.55	2.70		
Substitution rate for single-injection NB item 10.0% ±20% (\$ million)	1.85 to	1.95 to	2.04 to	2.15 to	2.25 to	2.37 to		
	2.11	2.21	2.32	2.44	2.56	2.69		
Use of catheter for peripheral NB	1.41 to	1.48 to	1.55 to	1.63 to	1.71 to	1.80 to		
22.0% ±20% (\$ million)	2.62	2.75	2.89	3.03	3.18	3.34		
Scenario analysis								
Include consultation fee prior to discharge (\$ million)	3.02	3.17	3.33	3.50	3.67	3.85		

Table 20 Sensitivity analysis calculation of net financial impact to MBS

Abbreviations: FY = financial year; MBS = Medicare Benefits Schedule; NB = nerve block, p.a. = per annum Source: DCAR Table 19

Should listing of the proposed item elicit an actual change in practice away from single-injection nerve blocks to continuous nerve blockade in some cases, there may be some additional impacts on the net financial impact calculations. In the ratified PICO, the applicant acknowledged that a consultation (claimed under MBS item 18222, 18225 or 17640 prior to discharge) may be required for a patient with a catheter nerve block as part of post-anaesthesia care. A scenario analysis considering the additional cost for this consultation as part of the intervention cost was associated with an estimated net financial impact to the MBS of approximately \$3.02 million in year 1 of listing (FY 2024–25; Table 19). However, these additional consultations would not be expected after all catheter nerve blocks, so expected costs were likely overestimated in this scenario. Moreover, such attendances may be required for any mode of postoperative analgesia; whether use of a catheter nerve block impacts the proportion of patients requiring such a consultation is unknown.

Moreover, should the proposed listing elicit a change in practice, the additional use of catheters and infusion pumps—in particular, an elastomeric infusion pump system, which has a unit cost of approximately \$300/patient—and anaesthesia medication (e.g. local anaesthesia medication such as ropivacaine) resulting from these substitutions would pose additional costs to hospitals and/or patients. The overall net financial impact of any such shifts may be offset by cost savings through reductions in opioid consumption and hospital length of stay; however, clinical evidence on these outcomes was mixed. These costs were not accounted for in the financial analyses presented.

15. Other relevant information

Nil.

16. Key issues from ESC to MSAC

Main issues for MSAC consideration

Clinical issues:

- There were uncertainties about the extent of assumptions that can be made based on the exemplar case of knee surgery. As the proposed MBS item would apply to a variety of indications and surgeries in a broad patient population, it was uncertain whether the findings from the exemplar case can be generalised to all other indications. The proportion of continuous nerve blocks that would be knee surgeries was not estimated.
- There was limited evidence for the use of continuous nerve block across other indications.
- There was a lack of evidence showing patient-centred experiences and outcomes, quality of life, length of hospital stay, and value-based care aspects such as overall costs of the procedure and clinical benefits.
- The applicant stated that usage of continuous nerve blocks is increasing and in many instances is becoming standard of care.

Economic issues:

- The cost-effectiveness analysis addressed pain but not reduction in post-operative opioid use. There was a lack of economic evidence addressing opioid reduction as a goal of the intervention.
- There was uncertainty in the interpretation of ICERs expressed in terms of cost per unit of improvement in pain.
- There was substantial uncertainty in the ICERs due to the lack of data. It may be helpful to present sensitivity analyses in terms of the impact on the ICER, not only on disaggregated costs and outcomes.
- There was a lack of economic evidence on surgical indications other than the exemplar case of knee surgery. There was uncertainty whether the exemplar case can be assumed to be typical, an upper bound, etc.
- ESC considered that the economic evaluation was likely of limited value for decision-making on this application, however ESC considered it was unlikely to be able to be improved in the near future due to the limited data available.

ESC discussion

ESC noted that this application from the Australian Society of Anaesthetists requested Medicare Benefits Schedule (MBS) listing of continuous peripheral nerve block for moderate to severe pain after limb or trunk surgery.

ESC noted that, in April 2017, MSAC had considered continuous catheter blockade of peripheral nerves for post-operative pain management (application 1308: local anaesthetic nerve blockade for post-surgical analgesia) in the context of a broader application encompassing minor, major and continuous peripheral nerve block. MSAC did not support application 1308 due to concerns with the population/patient cohort, broadness of the nerve block indications, clinical evidence, out-of-pocket expenses and health care gain. ESC noted the MBS Reviews Taskforce subsequently addressed the issues of plexus or nerve (minor and major) blocks via Recommendation 16 of the Anaesthesia Clinical Committee (ACC) Report, which saw the introduction of MBS item 22041 for perioperative introduction of a plexus or nerve block proximal to the lower leg or forearm for post operative pain management on 1 November 2019.

ESC noted nerve blockade has become more common in clinical practice since the original application and that continuous nerve block is approaching standard of care for several types of major joint surgery. In the absence of an MBS item for a continuous catheter, continuous nerve block may be being claimed under items for single-injection nerve block.

ESC noted that this treatment was proposed to be used for post-operative pain arising from any surgery likely to cause moderate to severe pain lasting 12 hours or more, such as joint arthroplasty and significant soft tissue injuries, that cannot be covered with a single-injection nerve block. Treatment would be pre-emptively offered based on an expectation of moderate to severe post-operative pain (and not after pain has manifested). ESC noted that continuous peripheral nerve block may be suitable if systemic opioids are not recommended for reasons such as opioid sensitivity, tolerance or dependence; or if there are co-morbidities rendering parenteral opioid administration inappropriate, such as respiratory insufficiency, asthma, head injuries, myasthenia gravis, or chronic pain before joint surgery. The use of continuous nerve block could also reduce routine opioid prescribing in the management of post-operative pain.

ESC noted and welcomed consultation input from 2 professional organisations, and 6 individuals, all of whom were medical specialists. ESC noted that consultation feedback, mostly from specialist medical practitioners, stated the benefits of continuous nerve block were the provision of constant analgesia, avoidance of opioids, enhanced recovery, reduced hospital stays and increased mobilisation. Feedback also noted the lack of evidence for safety and effectiveness of opioids. ESC noted feedback that the proposed fees were not likely to reflect the cost to the patient.

ESC considered that one of the main outcome measures was length of hospital stay. ESC considered that the length of a patient's hospital stay is influenced by many factors apart from pain management. Other factors influencing length of hospital stay may include upper vs lower limb (as upper limb patients can mobilise earlier), age, practice of the individual surgeon, availability of physiotherapy and rehabilitation services, collaboration between the surgeon and physiotherapists, supports available at home and differing practices between public and private hospitals.

ESC noted the MBS item descriptor was for post-operative pain management of limb and trunk surgeries. ESC considered the wording of the item descriptor to be reasonable. ESC noted that application 1308 included an 85% benefit for out-of-hospital use, as do the item descriptors for MBS item 22031 (intrathecal or epidural injection with or without a catheter for an initial injection) and MBS item 22036 (intrathecal or epidural injection using an in-situ catheter for a subsequent injection). ESC considered that a 75% benefit was more appropriate, based on the proposed use as a surgical item and that 85% would not be appropriate.

ESC noted the proposed addition to the treatment algorithm. Considerations for continuous nerve block include pain that is amendable to nerve block; settings where epidural anaesthesia would be inappropriate, contraindicated or ineffective due to anatomical considerations; in patients where simple parenteral opiate regimens are unsuitable (such as people who are very young, older, cognitively or physically disabled, opiate sensitive or dependent, or with co-morbidities); and in elective procedures with short planned post-operative stay. Although the procedure would be restricted to administration in an in-patient hospital setting, the applicant noted that a general practitioner (GP) anaesthetist may also undertake this procedure.

ESC noted that the clinical trial data supporting this application consisted of 21 studies, including 9 randomised controlled trials (RCTs) on knee surgery, 3 RCTs on trauma surgery and 9 systemic reviews of secondary indications. ESC noted that the department-contracted assessment report (DCAR) used an exemplar case of orthopaedic knee surgery as the basis for the clinical and economic evaluations. The decision to use an exemplar case was due to the broad range of indications within the overall eligible population. Knee surgery was chosen because it provided the strongest amount of evidence that aligned with the PICO criteria.

ESC considered that there were uncertainties about the assumptions that could be made about the position of the exemplar case in the variety of surgeries to which this item would apply. ESC questioned whether the exemplar case was typical in its cost-effectiveness, or whether it might represent an upper or lower bound. ESC considered that along with pain management there are many other variables that influence patient outcomes for total knee replacement, making it uncertain whether the findings from the exemplar case can be reasonably generalised to other indications. ESC considered that if the applicant could provide information on the estimated proportion of continuous nerve blocks that would be knee surgeries, this would help MSAC to consider the generalisability of the exemplar.

ESC considered that it was challenging to provide overall conclusions on the appropriateness of continuous nerve block due to the broad nature of the patient population and types of nerve block that would be eligible (that is, any limb or trunk surgery associated with moderate to severe post-operative pain), particularly when evidence for supplementary indications conflicted with the exemplar case. ESC noted that, to present evidence for the broadest range of indications, published systematic review evidence was presented for the supplementary indications. While efforts were made to select reviews that explicitly met the PICO criteria, some had applicability concerns relating to the interventions, comparators and/or supplementary or concomitant analgesia. For these reasons, the exemplar case presented the most directly applicable evidence to Australian practice, albeit for a subgroup of the overall eligible population. The application positioned continuous nerve block primarily as an alternative to single-injection nerve block for limb and trunk surgeries; however, evidence from the exemplar indication in relation to one of the secondary comparators (neuraxial nerve block) was insufficient to draw meaningful conclusions.

Regarding comparative safety, ESC noted that, for the exemplar case, there was no evidence available for mortality, local anaesthesia toxicity or block-related complications for continuous nerve block. Compared with single-injection nerve block (the primary comparator), two RCTs reported nausea and vomiting, and there was no statistically significant difference between the two methods. Compared with systemic opioids, three RCTs reported nausea and vomiting at 48 and 72 hours, with a statistically significant difference favouring continuous nerve block. Compared with neuraxial nerve block, one RCT reported nausea and vomiting, and there was no statistically significant difference block. Compared with neuraxial nerve block, one RCT reported nausea and vomiting, and there was no statistically significant difference between the two methods. Overall, ESC considered the applicant's claim of non-inferior safety was likely reasonable.

For comparative effectiveness, ESC noted the claims from the applicant that in comparison to the available alternatives a continuous nerve block allows reduced length of stay in hospital; earlier mobilisation and faster recovery time; decreased rates of opioid use and prescribing, and therefore, the potential for reduced opioid dependence; better post-operative pain control (especially reduction of rebound pain), better ongoing analgesia, and prevention of development of chronic pain due to better post-operative pain management; and less pressure on hospital resources. ESC recalled that, in its review of application 1308 at its April 2017 meeting, MSAC had expressed concern that data on the length of hospital stay, recovery time, post-surgical chronic pain and quality of life were very limited or not presented. Patient-centred outcomes were also lacking. MSAC had considered that, if available, these data may have enabled a cost-utility analysis to assist decision-making. ESC noted that these outcomes were also missing from the RCTs included in this application but considered that trial data on reduced length of hospital stay were unlikely to become available. Additionally, ESC noted that in its experience, patients who have had surgery performed on their lower limbs may have longer hospital stays than patients who have had surgery involving their upper limbs, due to decreased mobilisation. ESC therefore considered this raised uncertainty around the applicability of the effectiveness evidence for the exemplar.

ESC noted that for the exemplar case, compared with single-injection nerve block (the primary comparator), three RCTs reported statistically significant differences for patient-reported post-operative pain scores at 48 hours in favour of continuous nerve block. There were no significant

differences between 48 and 72 hours post-operatively. Compared with systemic opioids, one RCT reported statistically significant differences for opioid consumption for breakthrough pain at 72 hours post-operatively in favour of continuous nerve block, one RCT reported a significantly lower incidence of chronic post-operative pain at 3 and 6 months post-operatively in favour of continuous nerve block, and two RCTs reported a statistically significant difference for block reattempt or failure at 48–72 hours post-operatively in favour of systemic opioids. There were no differences in patient-reported post-operative pain scores, patient satisfaction, supplementary analgesia or hospital length of stay. Compared with neuraxial block, two RCTs reported statistically significant differences in the use of rescue analgesia at 48–72 hours post-operatively in favour of continuous nerve block, one RCT reported opioid consumption for breakthrough pain at 48 hours post-operatively in favour of continuous nerve block, and one RCT reported statistically significant patient satisfaction in favour of continuous nerve block. ESC considered the effectiveness evidence was inconsistent in direction between the different comparators.

Overall, ESC considered that, for patients undergoing knee surgery for moderate to severe postoperative pain expected to last 12 hours or longer, the effectiveness evidence suggested that continuous peripheral nerve block had:

- superior effectiveness (based on uncertain evidence) and non-inferior safety compared to single-injection nerve block
- superior effectiveness (based on uncertain evidence) and non-inferior safety compared to systemic opioids.

ESC considered there was insufficient evidence to draw conclusions on the relative effectiveness of continuous peripheral nerve block compared to neuraxial nerve block.

ESC noted that given the reported current wide utilisation of continuous nerve blocks for postoperative pain management, significant implementation issues were not anticipated for use in hospital in-patients. ESC noted there are no guidelines for ambulatory patients, so use in these patients is the responsibility of hospitals, where quality programs already exist.

ESC noted that the economic evaluation was a cost-effectiveness analysis (CEA) using a simple decision tree structure and a time horizon of 5 days, against the primary comparator of single nerve block. The outcome was improvement in post-operative pain, as measured on a 10-point visual analogue scale. ESC noted that the PICO stated that a cost-utility analysis would be appropriate, but agreed with the DCAR that this was infeasible due to the lack of available evidence and short time horizon.

ESC considered that the pain scale outcome may not fully capture the clinical need, nor outcomes such as mobilisation and early discharge from hospital. ESC noted that there were two elements described in the clinical need: the medical necessity of managing post-operative pain and the need to reduce routine opioid prescriptions. ESC considered that the CEA only addressed the first element. Differences in rescue analgesia captured opioids as a cost item but not as an outcome or benefit (that is, it did not capture the impact on opioid consumption except as a cost). ESC also considered it was unclear how rescue analgesia related to risk of opioid dependency. The parameter included in the evaluation was any or no rescue analgesia, but ESC questioned whether the total consumption of opioids in the postoperative period might better reflect the risk of dependency. ESC considered that there was a mismatch between the rationale for the intervention and the economic evidence but acknowledged that this was probably unavoidable given the limitations of the data.

ESC noted the DCAR reported the ICER was \$114.35 per unit of pain improvement on a 10-point visual analogue scale, and that the mean difference in pain in the base case was -1.35. However, ESC considered that a considerable limitation of the economic evaluation was that it was difficult to contextualise the value of a one-unit improvement in pain. ESC noted that a study by Laigaard et al. (2021)²² reported a minimal clinically important difference in pain of 15 mm and considered that this may be equivalent to a change in pain score of 1.5 units on a 10-point scale, although it did not capture quality of life. ESC noted that the DCAR stated that it was not possible to incorporate other relevant outcomes into the model, such as health-related quality of life, rate of chronic pain and risk of opioid dependency.

ESC noted that the key drivers of the model were effectiveness payoff (post-operative pain), relative duration of hospital stay, relative out-of-pocket costs for the nerve block procedure, and whether the continuous nerve block was performed in inpatient or ambulatory setting. ESC considered that the extent of impact was described relative to the base case, and so it was hard to gauge whether an impact was meaningful given the uncertainty around the value of a one-unit improvement in pain in the first place. ESC noted the pre-ESC response that ultrasound costs should not be included, however ESC considered that, because the perspective is that of the healthcare system, hospital costs including ultrasound costs were relevant.

ESC considered there was a high degree of uncertainty in the input data for hospital length of stay (not reported for the exemplar case), which had a large impact on incremental cost. Additionally, rehospitalisation due to pain was proposed in the PICO but was not captured in the model (as it was not reported for the exemplar case).

ESC considered that the economic evaluation was likely of limited value for decision-making on this application, however ESC also considered it was unlikely to be able to be improved in the near future due to the limited data available.

Regarding out-of-pocket costs, ESC noted that there was a gap of \$206.88 between the estimated cost for the service (\$315.88) and the proposed MBS fee (\$109.00). Adding 25% of the MBS fee increased the gap to \$234.13. ESC noted that there were no data on out-of-pocket costs for the comparator, so the base case assumed they were equal to the costs for the intervention. For MBS item 22031, in the private setting in 2021–22, 98% of services had out-of-pocket costs, typically \$204. No out-of-pocket cost data were available for MBS item 22041 so there was no evidence of incremental difference between the intervention and comparator costs for this element.

ESC noted that the proposed fee corresponded to a value of 5 basic units as per the relative value guide for anaesthesia, and that this was the same level of complexity as for MBS item 22031. ESC considered that this was appropriate for the proposed item, and that it would be performed by clinicians with a variety of experience. Continuous nerve block can be done pre-operatively by the anaesthetists who will be involved in the peri-operative care of patients. Typically for less experienced clinicians the continuous nerve block may take 40-60 minutes to perform, while for experienced clinicians, it may take 5–10 minutes.

ESC noted the pre-ESC response stated that costs would be offset by shorter hospital stays and reductions in opioid use. However, as noted, length of stay was not reported in the RCTs for the exemplar case (this was partially addressed in the sensitivity analysis, using a 95% confidence interval for length of stay). The applicant's pre-ESC response also asked that the committee consider that reduced length of stay may enable more patients to be treated, therefore increasing the hospital's capacity to conduct additional episodes of care. However, ESC considered that this was appropriately omitted from the base-case analysis as hospital capacity is not directly related to the resources or health outcomes for the patient population. ESC noted the MSAC Guidelines²³ state that discussion of 'organisational aspects' (consequences that flow

²² Laigaard, J., Pedersen, C., Rønsbo, T. N., Mathiesen, O. & Karlsen, A. P. H. 2021. Minimal clinically important differences in randomised clinical trials on pain management after total hip and knee arthroplasty: a systematic review. *Br J Anaesth*, 126, 1029-1037

²³ MSAC Guidelines, Technical Guidance 29.3. http://www.msac.gov.au/internet/msac/publishing.nsf/Content/MSAC-Guidelines

from implementation in the organisation of the healthcare system) may be included in assessments under 'other relevant considerations'.

ESC noted that the net financial impact to the MBS was estimated to be \$1.98 million in year 1 increasing to \$2.53 million in year 6. ESC noted that the financial impacts assumed substitution of MBS item 22041 (but not for MBS items 22031 or 22036). ESC considered that it was uncertain whether this would be a true shift or change in claiming. ESC noted PASC had advised that 10% would be a true substitution, while there was 22% catheter use in the Australian and New Zealand Registry of Regional Anaesthesia. ESC also noted that the financial impacts assumed a 5% annual growth in the number of peripheral nerve blocks.

ESC considered whether, like other procedures performed in hospital, aftercare should be included as part of the service. ESC noted that the department's policy preference that aftercare should not be included for this service, as it is not included in other MBS items involving anaesthesia.

17. Applicant comments on MSAC's Public Summary Document

The applicant had no comment.

18. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: <u>visit the MSAC website</u>