

Population

Describe the population in which the proposed health technology is intended to be used:

Patients with intractable peripheral neuropathic pain that does not respond to standard treatment such as, physical, psychological and/or pharmacological therapies. PENS is intended to provide symptomatic pain relief in adults only.

Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed health technology, describing how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the technology:

Patients 18 years of age and over. Patients will be experiencing chronic peripheral neuropathic pain, with indications including but not limited to:

Peripheral neuropathic pain

- Occipital Neuralgia
- Cluster Headache
- Supra-orbital Neuralgia
- Trigeminal Neuralgia
- Intractable Facial Pain
- Post Hernia Repair Pain
- Neuropathic Chest Wall Pain
- Post Mastectomy Pain
- Stump Pain

Patients may be seen initially by a General Practitioner (GP) for advice on chronic pain which has typically lasted for more than 3 months. Other specialists, e.g. neurologists may also be consulted. If pain does not resolve patients can be referred to pain clinics or a pain specialist via their GP or other specialist.

Pain management may start with pharmacological intervention. A multidisciplinary approach may include psychologists, physiotherapists and non-medical interventions such as exercise, nutrition and improving sleep.

If pain is ongoing a patient may be referred to a pain management proceduralist physician who may consider PENS therapy which is a minimally invasive procedure.

Provide a rationale for the specifics of the eligible population:

Neurostimulation of the brain, spinal cord or peripheral nerves has been introduced as a treatment option for patients whose condition is unresponsive to other forms of treatment. PENS therapy is a useful non-pharmacological adjuvant to neuropathic pain medications and opioids thus avoiding the problem of tolerance and physical dependence that is associated with long-term opioid use. PENS therapy can also be used in areas of hyperalgesia and allodynia where the patient cannot tolerate TENS application directly onto the skin.

Peripheral nerve stimulation is gaining popularity as a method of managing patients with

hyperalgesia (an increased sensitivity to painful stimuli) and allodynia (painful reaction to otherwise non-painful stimuli). The Algotec NeuroStimulator PENS therapy system devices were developed in response to these patients as it provides a minimally invasive method for percutaneously delivering electrical stimulation directly to peripheral nerves for a brief period of time, to induce analgesic effects and facilitate a normalisation of central processing, without the risks associated with further surgery.

Are there any prerequisite tests?

No

Intervention

Name of the proposed health technology:

Percutaneous Electrical Nerve Stimulation (PENS) therapy

Describe the key components and clinical steps involved in delivering the proposed health technology:

PENS therapy does not require complex surgical implantation, since the Probe electrode for stimulation is removed after the therapy. Treatment can be performed on a day only basis. Percutaneous Electrical Nerve Stimulation (PENS) therapy refers to stimulation of individual named peripheral nerve(s) or unnamed peripheral nerve endings using needle Probes. Either one or two 21 gauge Probes are inserted into soft tissues near the targeted nerve(s). The Probes are connected to a low-voltage pulse generator (NeuroStimulator) and an electrical current is then applied to generate a sensation of paraesthesia. The duration of treatment varies but each session typically lasts 25 minutes. Please see the attached 'Image 1' for images of the PENS therapy system

Identify how the proposed technology achieves the intended patient outcomes:

PENS therapy uses disposable 21-gauge Probes electrodes with three program options available, program A, B and C. The default program is program C, which is continuous alternating/cycling between program A and program B, alternating every 3 s for a total therapy duration of 25 minutes. Program A has a pulse width of 0.2 ms and frequency of 100 Hz, whereas program B has a pulse width of 1.0 ms and frequency of 2 Hz. The stimulation is delivered for 25 min at alternating frequency of 2 and 100 Hz every 3 s (program C). Amplitude is set to patient perception and varies between 0.1 and 6.V The cylindrical percutaneous type Probe electrode has improved the access to the sensory afferents in head and face regions as well as extremity peripheral nerves.

The alternating frequencies of PENS therapy Program C is somewhat similar to methods used in Electro-acupuncture (Han, 2003) which is intended to facilitate the release of specific neuropeptides in the central nervous system, by cycling low frequency stimulation - accelerating the release of enkephalin, b-endorphin and endomorphin and high frequency stimulation – selectively accelerating the release of dynorphin. The combination of these two frequencies

produces a simultaneous release of all four opioid peptides resulting in a more effective therapy than stimulation at either one or the other frequency.

It is proposed that endogenous opioid peptides in the central nervous system play an essential role in mediating the analgesic effect of PENS therapy, and that prolonged pain relief is achieved through the delivery of frequency dependant electrical pulses (Ansarinia et al., 2010).

When used on carefully selected chronic neuropathic pain patients, PENS therapy may;

- Reduce pain through induced analgesia
- Increase activity and independence levels
- Reduce use of narcotic medications
- Reduce hospitalisations and surgical procedures,
- Reduce healthcare costs
- Improve quality of life

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?

Yes

Explain whether it is essential to have this trademark component or whether there would be other components that would be suitable:

The term 'NeuroStimulator PENS therapy' is trademarked. This refers to the system which includes the NeuroStimulator (pulse generator), PENS therapy Probes and the stimulation algorithm described above. At present the applicant is not aware of any other manufacturer or sponsor that provides a similar technology in Australia, but it is possible that one may emerge in the future.

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):

No

Provide details and explain:

N/A

If applicable, advise which health professionals will be needed to provide the proposed health technology:

Specialist pain medicine physician

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:

No

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:

No

Is there specific training or qualifications required to provide or deliver the proposed service, and/or any accreditation requirements to support delivery of the health technology?

Yes

Provide details and explain:

A doctor must meet the requirements to qualify as a fellow of the Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists (FFPMANZCA). This is a post specialist qualification and doctors may have another specialist qualification such as anaesthesiology, medicine, surgery, psychiatry or rehabilitation medicine

Indicate the proposed setting(s) in which the proposed health technology will be delivered:
(select all relevant settings)

- Consulting rooms
- Day surgery centre
- Emergency Department
- Inpatient private hospital
- Inpatient public hospital
- Laboratory
- Outpatient clinic
- Patient's home
- Point of care testing
- Residential aged care facility
- Other (please specify)

Setting	Rationale
Day surgery centre	PENS therapy requires the use of an operating theatre and the procedure is performed under ultrasound guidance.
Inpatient private hospital	The procedure may be performed at an inpatient hospital on a day only basis
Inpatient public hospital	The procedure may be performed at an inpatient public hospital on a day only basis

Is the proposed health technology intended to be entirely rendered inside Australia?

Yes

Please provide additional details on the proposed health technology to be rendered outside of Australia:

N/A

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Comparator name	Comparator type
Neurostimulator or receiver, subcutaneous placement of, including placement and connection of extension wires to epidural or peripheral nerve electrodes, for the management of chronic neuropathic pain or pain from refractory angina pectoris (H) (Anaes.) (Assist.)	MBS
Peripheral nerve lead or leads, surgical placement of, including intraoperative test stimulation, for the management of chronic neuropathic pain where the leads are intended to remain in situ long term (H) (Anaes.) (Assist.)	MBS
Professional attendance at consulting rooms or hospital by a specialist, or consultant physician, in the practice of the specialist's or consultant physician's specialty of pain medicine following referral of the patient to the specialist or consultant physician by a referring practitioner-each attendance (other than a service to which item 2814 applies) after the first in a single course of treatment	MBS

List any existing MBS item numbers that are relevant for the nominated comparators:**Comparator 1 - MBS****Type:** MBS**MBS Item:** 39134

MBS Item descriptor: Neurostimulator or receiver, subcutaneous placement of, including placement and connection of extension wires to epidural or peripheral nerve electrodes, for the management of chronic neuropathic pain or pain from refractory angina pectoris (H) (Anaes.) (Assist.)

Please provide a description of the comparator: Implantation of a permanent neurostimulator (39134) and implantation of leads (39138) together form the permanent neurostimulator system for the delivery of electrical stimulation for the treatment of chronic neuropathic pain.

Please provide a rationale for why this is a comparator:

In the absence of PENS therapy, implantation of a permanent device incorporating leads and a pulse generator would be an option for these patients.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?

- None – used with the comparator
- Displaced – comparator will likely be used following the proposed technology in some patients
- Partial – in some cases, the proposed technology will replace the use of the comparator, but not in all cases
- Full – subjects who receive the proposed intervention will not receive the comparator

Please outline and explain the extent to which the current comparator is expected to be substituted:

PENS therapy is also intended to identify patients who will be unlikely to benefit from use of the comparator. Hence there may be an additional decrease in the use of the comparator. At present PENS therapy is delivered approximately 1500 times a year based on the applicants sales data. This may represent the same patient receiving the therapy 2-3 times a year but this rate may be slightly more or less. It is not possible to calculate the number of individual patients but is likely to be a small proportion of those receiving the comparator. As the therapy is adopted, it is anticipated that a slightly greater proportion of those receiving permanent implants may use PENS therapy instead

Comparator 2 - MBS

Type: MBS

MBS Item: 39138

MBS Item descriptor: Peripheral nerve lead or leads, surgical placement of, including intraoperative test stimulation, for the management of chronic neuropathic pain where the leads are intended to remain in situ long term (H) (Anaes.) (Assist.)

Please provide a description of the comparator: Implantation of leads (39138) and an implantable pulse generator (IPG) together form the permanent neurostimulator system (39134) for the delivery of electrical of electrical stimulation to peripheral nerves for the treatment of chronic neuropathic pain.

Please provide a rationale for why this is a comparator:

In the absence of PENS therapy, implantation of a permanent electrode lead and use of a Pulse Generator would be the alternative option for these patients.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator? (please select your response)

- None – used with the comparator
- Displaced – comparator will likely be used following the proposed technology in some patients
- Partial – in some cases, the proposed technology will replace the use of the comparator, but not in all cases
- Full – subjects who receive the proposed intervention will not receive the comparator

Please outline and explain the extent to which the current comparator is expected to be substituted:

PENS therapy is also intended to identify patients who will be unlikely to benefit from use of the comparator. Hence there may be an additional decrease in the use of the comparator. At present PENS therapy is a small proportion of those receiving permanent implants. As the therapy is adopted, it is anticipated that a greater proportion of those receiving permanent implants may use PENS therapy instead.

Comparator 3 - MBS

Type: MBS

MBS Item: 2806

MBS Item descriptor: Professional attendance at consulting rooms or hospital by a specialist, or consultant physician, in the practice of the specialist's or consultant physician's specialty of pain medicine following referral of the patient to the specialist or consultant physician by a referring practitioner-each attendance (other than a service to which item 2814 applies) after the first in a single course of treatment

Please provide a description of the comparator: A consultation with a consultant pain physician to provide pain management for chronic neuropathic pain

Please provide a rationale for why this is a comparator:

In the absence of PENS, a patient would be managed by a pain physician using other methods of pain management

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?

- None – used with the comparator

- Displaced – comparator will likely be used following the proposed technology in some patients
- Partial – in some cases, the proposed technology will replace the use of the comparator, but not in all cases
- Full – subjects who receive the proposed intervention will not receive the comparator

Please outline and explain the extent to which the current comparator is expected to be substituted:

N/A

Outcomes

Outcome no.	Outcome type	Outcome name
1	Health benefits	Quality of Life
2	Health benefits	Pain reduction
3	Resources	Reduction in narcotic medication
4	Resources	Reduction in implantation of neurostimulators

Outcome 1 – Quality of Life

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator): (please select your response)

- Health benefits
- Health harms
- Resources
- Value of knowing

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The intervention is not a test

Outcome 2 – Pain reduction

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator): (please select your response)

- Health benefits
- Health harms
- Resources
- Value of knowing

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The intervention is not a test

Outcome 3 – Reduction in narcotic medication

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator): (please select your response)

- Health benefits
- Health harms
- Resources
- Value of knowing

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

Reduced use of narcotic medication due to pain reduction

Outcome 4 – Reduction in implantation of neurostimulators

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator): (please select your response)

- Health benefits
- Health harms
- Resources
- Value of knowing

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

Reduction in use of permanent neurostimulators as patients may receive sufficient reduction in pain with the use of PENS to make permanent implantation unnecessary, or patients may have no reduction in pain from PENS therapy in which case would be unlikely to benefit from a permanently implanted neurostimulator

Proposed MBS items

How is the technology/service funded at present? (for example: research funding; State-based funding; self-funded by patients; no funding or payments):

Please provide at least one proposed item with their descriptor and associated costs, for each population/Intervention: (please copy the below questions and complete for each proposed item)

Proposed item details

MBS item number (where used as a template for the proposed item)	39129
Category	THERAPEUTIC PROCEDURES
Group	SURGICAL OPERATIONS
Proposed item descriptor	Peripheral lead or leads, percutaneous placement of, including intraoperative test stimulation, for the management of chronic neuropathic pain (H) (Anaes.) (Assist.)
Proposed MBS fee	\$641.40
Indicate the overall cost per patient of providing the proposed health technology	\$2,906.75
Please specify any anticipated out of pocket expenses	\$1,000.00
Provide any further details and explain	The cost per hospitalisation is assumed to be that of AR-DRG B71B (Cranial and peripheral nerve disorders, minor complexity). Fees for the pain proceduralist are incurred assumed to be those of MBS 39129. There are item numbers for anaesthesia, assumed to be 20300 and 23025. The cost for the PENS therapy Probes are \$400. There are likely to be out of pocket costs in the form of gap payments to the pain proceduralist and the anaesthetist. As these are a matter of discretion for the medical practitioners involved, they can not be estimated with any certainty. The amount has been assumed to be \$1000 but may be more or less than this amount.

Algorithms

Preparation for using the health technology

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, before patients would be eligible for the proposed health technology:

A patient with chronic neuropathic pain is likely to be referred to a pain physician when pain has not been resolved by a general practitioner or other treating specialist (e.g. neurologist). A multidisciplinary approach should include: psychologists, physiotherapists and non-medical interventions such as exercise, nutrition and improving sleep and should be implemented prior to considering PENS therapy:

- Patients are assessed for pain using a pain rating score such as the 2008 IASP Pain Terminology (Haanpää M, 2011).
- Pain lasting > 3 months
- Pain severe in grade (NRS \geq 7)
- Localised pain able to be treated with one or two Probes
- No localised infection
- No irreversible increased bleeding tendency
- Pain refractory to pharmacological therapies
- In the case of the allodynia and hyperalgesia this needs to be in an area supplied by a peripheral nerve that is accessible and able to be targeted by the PENS probe, or in a circumscribed region that is accessible to the PENS probe

Is there any expectation that the clinical management algorithm *before* the health technology is used will change due to the introduction of the proposed health technology?

No

Describe and explain any differences in the clinical management algorithm prior to the use of the proposed health technology vs. the comparator health technology:

N/A

Use of the health technology

Explain what other healthcare resources are used in conjunction with delivering the proposed health technology:

The PENS therapy procedure is performed in an operating theatre with local anaesthesia. Ultrasound imaging is used to locate the peripheral nerve to be treated. The PENS NeuroStimulator (pulse generator) is required. This is a durable item and is usually loaned to the treating facility and does not need to be purchased. The needle Probes are a single use item and either one or two are used for each procedure. The procedure also requires a limited re-use dual intermediate cable, a limited re-use return electrode cable (supplied on loan as part of the NeuroStimulator) and a hospital approved, disposable return electrode pad (single plated).

Explain what other healthcare resources are used in conjunction with the comparator health technology:

Implantation of a permanent peripheral nerve neurostimulator device requires a trial of peripheral nerve stimulation prior to implantation to see if the therapy is effective. This requires the implantation of temporary leads in theatre with a trial of 7-10 days. If the trial is successful, a second procedure is undertaken and the permanent lead with tines to secure the electrode near the peripheral nerve is implanted. The service requires the use of a clinician programmer, and the patient is supplied with an external pulse generator and patient programmer. The external pulse generator is attached to disposable electrodes which sit over the implanted lead. The electrodes must be replaced every two or three days. This service is conducted in an operating theatre and also requires the use of both ultrasound and xray. Alternatively, a neurostimulator usually used for spinal cord stimulation may be used on a peripheral nerve. These leads do not have tines and may migrate away from the target nerve requiring revision surgeries. This device requires the permanent implantation of the pulse generator as well as the leads.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:

The PENS procedure is conducted as required but typically once or twice a year. It is typically considered impractical as an ongoing therapy if it must be performed in less than 3 month intervals. The resources described above are used at each procedure. Patients may receive relief for long periods (many months or years) but this varies between patients.

In contrast, the implanted neurostimulator requires a permanently implanted lead with associated external devices (programmer and pulse generator) as durable components. There is an ongoing need for disposable electrodes.

Clinical management after the use of health technology

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the proposed health technology:

PENS therapy may assist the physician in determining whether a patient is likely to benefit from a peripherally implanted stimulation device:

- If PENS therapy effective for > 3 months - repeat PENS therapy as required
- IF PENS therapy is effective for but < 3 months a PNS implant is appropriate

If PENS is unsuccessful, then there is no need for a trial of a permanent peripherally nerve stimulation implant as it is unlikely to be successful. PRF may be re-trialled, if there is no pain relief or relief is for < 3 months than the patient must continue to be managed by the pain physician with alternative measures

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the comparator health technology:

Should the trial of the peripheral nerve stimulation be successful and the patient receive a permanent implant, the patient would continue to use the stimulator as required. The pulse

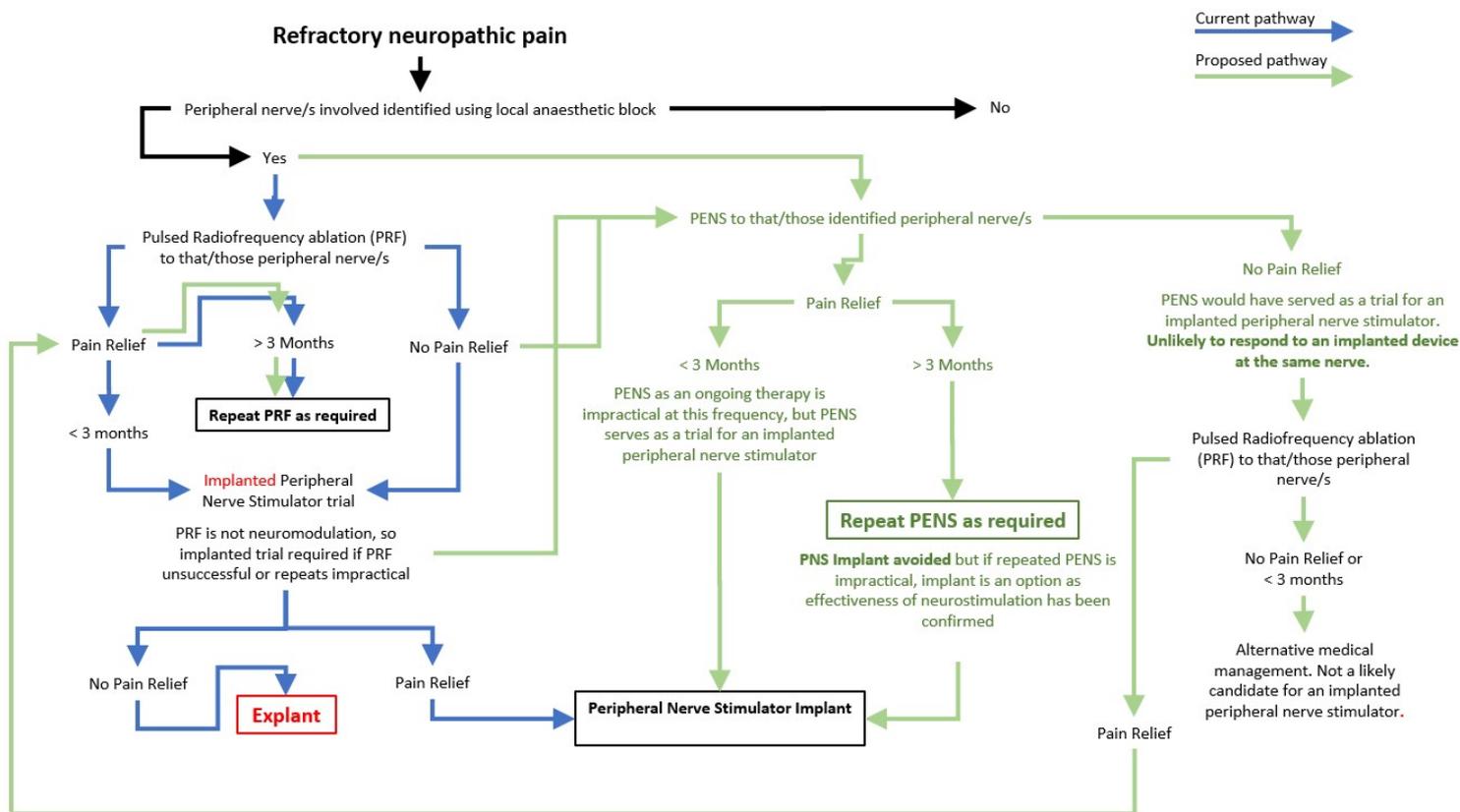
generator is likely to be replaced after 3-4 years. An External Pulse Generator (EPG) would require replacement every 5-10 years. The patient would return to the implanting physician/pain specialist for reprogramming of the IPG as and when required over the lifetime of the device (MBS 39131). If the lead/s migrated away from the target nerve, they would either be explanted (MBS 39136) or revised (MBS 39137). If the permanently implanted device ultimately failed to provide pain relief or became infected, it would be explanted (MBS 39136 and 39135). Patient programmers (included on the Prostheses List (PL) require replacement from time to time.

Describe and explain any differences in the healthcare resources used after the proposed health technology vs. the comparator health technology:

The PENS therapy may need to be repeated at varying intervals. Both therapies require ongoing management by a pain physician. Management by a pain physician is also a comparator and may require pharmaceutical or other multidisciplinary management

Algorithms

Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:



Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)? (please select your response)

- Superior
 Non-inferior
 Inferior

Please state what the overall claim is, and provide a rationale:

PENS therapy is likely to be superior to medical management for those patients who are eligible for PENS. PENS is likely to be non-inferior to a permanent implant with superior safety.

In terms of the immediate costs of the proposed technology (and immediate cost consequences, such as procedural costs, testing costs etc.), is the proposed technology claimed to be more costly, the same cost or less costly than the comparator? (please select your response)

- More costly
 Same cost
 Less costly

Provide a brief rationale for the claim:

Patients who are eligible for PENS therapy have failed all conventional pain management options. Should PENS therapy be successful then there is an assumption that it is superior to medical management. As PENS therapy uses the same mechanism of action for treating neuropathic pain as an implantable device then PENS therapy is likely to be non-inferior to an implantable device in suitable patients.

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement', please do not attach full text articles; just provide a summary (repeat columns as required).

Identify yet-to-be-published research that may have results available in the near future (that could be relevant to your application). Do not attach full text articles; this is just a summary (repeat columns as required).

Evidence no.	Citation	Published?	Attached file
1	Hall, S., & Vajramani, G. (2021). 'Nummular Headache Successfully Managed With Percutaneous Electrical	Published	Yes

	Nerve Stimulation: A Case Report.' Neuromodulation: Technology at the Neural Interface, 24(6), 1132–1134		
2	Vajramani G. 'Percutaneous Electrical Nerve Stimulation for Facial Pain. Prog Neurol Surg'. 2020; 35:45-59	Published	No
3	Rossi M,et al 'A Novel Mini-invasive Approach to the Treatment of Neuropathic Pain: The PENS Study' Pain Physician. 2016 Jan;19(1):E121-8	Published	No
4	Raphael, J.H et al 'Randomized Double- Blind Sham-Controlled Crossover Study of Short-Term Effect of Percutaneous Electrical Nerve Stimulation in Neuropathic Pain', Pain Medicine, Volume 12, Issue 10, October 2011, Pages 1515–1522	Published	No
5	Weiner DK, et al. 'Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial'. Pain. 2008 Nov 30;140(2):344-357	Published	No
6	Hamza MA et al 'Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain' Diabetes Care, 2000 Mar;23(3):365-70.	Published	No
7	Hamza, M. A et al. 'Effect of the Duration of Electrical Stimulation on the Analgesic Response in Patients with Low Back Pain' Anesthesiology, 1999, 91(6), 1622	Published	Yes

Evidence 1

Evidence number: 1

Type of evidence/study design: case report

Published? Published

Citation: Hall, S., & Vajramani, G. (2021). 'Nummular Headache Successfully Managed With Percutaneous Electrical Nerve Stimulation: A Case Report.' *Neuromodulation: Technology at the Neural Interface*, 24(6), 1132–1134

Description and relevance of citation: Nummular headache is localized scalp pain, a disorder of a terminal peripheral scalp nerve. Usual treatment is oral analgesics. A male patient received six PENS procedures over four years. There was a noticeable cumulative effect. When the effect of PENS wore off after three to four months, the hypersensitivity pain recurred gradually over two weeks, but was less severe.

Publication date/ estimated publication date: 15/03/2021

Please select whether the evidence is an attachment or a website link: Attachments

Attached file(s): Girish Nummular Headache Successfully Managed With Percutaneous Electrical Nerve Stimulation.pdf

Evidence 2

Evidence number: 2

Type of evidence/study design: Review Article

Published? Published

Citation: Vajramani G. 'Percutaneous Electrical Nerve Stimulation for Facial Pain. *Prog Neurol Surg*'. 2020; 35:45-59

Description and relevance of citation: A summary of PENS literature and discussion of PENS therapy mechanism of action, effect on facial pain, the technical background of PENS. Highlights advantages of PENS

- Does not involve implantation of permanent and expensive pulse generators
- Does not require complex surgical implantation
- Can be performed in a day only setting

Publication date/ estimated publication date: 22/07/2020

Please select whether the evidence is an attachment or a website link: Website

Website link: <https://pubmed.ncbi.nlm.nih.gov/32702693/>

Evidence 3

Evidence number: 3

Type of evidence/study design: Multicentre prospective observational study

Published? Published

Citation: Rossi M, et al 'A Novel Mini-invasive Approach to the Treatment of Neuropathic Pain: The PENS Study' *Pain Physician*. 2016 Jan;19(1):E121-8

Description and relevance of citation: Multi-centre, prospective, observational study. 4 Italian pain centres.

Rossi M, et al 'A Novel Mini-invasive Approach to the Treatment of Neuropathic Pain: The

PENS Study' Pain Physician. 2016 Jan;19(1):E121-8. N =76

Evaluate the short- and long-term efficacy of a single probe and single shot PENS approach. NRS and NPS decreased significantly after 60 minutes and the reduction remained constant over time at follow-up.

Two non-clinically significant adverse events (one contralateral dysesthesia and one self-resolving hematoma) were observed.

Publication date/ estimated publication date: 19/01/2016

Please select whether the evidence is an attachment or a website link: Website

Website link: <https://pubmed.ncbi.nlm.nih.gov/26752480/>

Evidence 4

Evidence number: 4

Type of evidence/study design: Randomised double-blind sham-controlled crossover study> PENS compared to sham PENS

Published? Published

Citation: Raphael, J.H et al 'Randomized Double-Blind Sham-Controlled Crossover Study of Short-Term Effect of Percutaneous Electrical Nerve Stimulation in Neuropathic Pain', Pain Medicine, Volume 12, Issue 10, October 2011, Pages 1515–1522

Description and relevance of citation: Studied 31 adult patients with hyperalgesia with various chronic pain conditions where conservative measures such as medication and TENS had failed. The NRS for pain changed from 7.5 (range 6–10) before therapy to 0.5 (range 0–8.5) after therapy. PENS therapy appears to be effective in providing short-term pain relief in chronic pain conditions.

Publication date/ estimated publication date: 21/10/2011

Please select whether the evidence is an attachment or a website link: Website

Website link:

<https://academic.oup.com/painmedicine/article/12/10/1515/1890387?login=false>

Evidence 5

Evidence number: 5

Type of evidence/study design: Randomised controlled trial

Published? Published

Citation: Weiner DK, et al. 'Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial'. Pain. 2008 Nov 30;140(2):344-357

Description and relevance of citation: N= 200 ≥ 65 years old.

Patients with chronic lower back pain treated with PENS. Randomised to receive:

1. PENS
2. Control-PENS (brief electrical stimulation)
3. PENS + GCAE
4. Control-PENS + GCAE

All four groups experienced significantly reduced pain (range -2.3 to -4.1 on the McGill Pain Questionnaire short form)

Publication date/ estimated publication date: 08/10/2017

Please select whether the evidence is an attachment or a website link: Website

Website link: <https://pubmed.ncbi.nlm.nih.gov/18930352/>

Evidence 6

Evidence number: 6

Type of evidence/study design: Randomised controlled blinded crossover study

Published? Published

Citation: Hamza MA et al 'Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain' *Diabetes Care*, 2000 Mar;23(3):365-70.

Description and relevance of citation: Patients with Type-2 diabetes and peripheral neuropathic pain in lower extremities assigned to PENS or Sham-PENS for 3 weeks. Pain VAS scores before active (6.2 ± 1.0) and sham (6.4 ± 0.9) treatments, pain scores after treatment were reduced to 2.5 ± 0.8 and 6.3 ± 1.1 , respectively.

Publication date/ estimated publication date: 01/03/2000

Please select whether the evidence is an attachment or a website link: Website

Website link: <https://diabetesjournals.org/care/article/23/3/365/20843/Percutaneous-electrical-nerve-stimulation-a-novel>

Evidence 7

Evidence number: 7

Type of evidence/study design: Randomised sham-controlled crossover study

Published? Published

Citation: Hamza, M. A et al. 'Effect of the Duration of Electrical Stimulation on the Analgesic Response in Patients with Low Back Pain' *Anesthesiology*, 1999, 91(6), 1622

Description and relevance of citation: Patients with low back pain. PENS produced short-term improvements in the VAS pain, physical activity, and quality of sleep scores, and a reduction in the oral analgesic requirements. The 30-min and 45-min durations of electrical stimulation produced similar hypoalgesic effects ($48 \cdot 21\%$ and $46 \cdot 19\%$, respectively).

Publication date/ estimated publication date: 01/12/1999

Please select whether the evidence is an attachment or a website link: Attachments

Attached file(s): hamza1999.pdf