

MSAC Application 1739

**Percutaneous Electrical Nerve
Stimulation (PENS) therapy for chronic
neuropathic pain**

Application for MBS eligible service or health technology

MSAC Application Number

1739

Application title:

Percutaneous Electrical Nerve Stimulation (PENS) therapy for chronic neuropathic pain

Submitting organisation:

WURLEY GROUP PTY LTD

Submitting organisation ABN:

13100392827

Application description

Succinct description of the medical condition/s:

Chronic intractable neuropathic pain is pain caused by lesions or dysfunction in the nervous system and does not respond to standard treatment.

Succinct description of the service or health technology:

Percutaneous Electrical Nerve Stimulation (PENS) therapy is stimulation of individual nerves using needles which are inserted into soft tissues near the targeted nerve or in areas under the skin where the pain occurs. The Probe electrodes are connected to a low-voltage pulse generator and an electrical current is then applied to generate a sensation of 'pins and needles' or numbness.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Lobbyist

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name: Algotec Research and Development Limited

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prostheses List?

No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

Amendment

What is the nature of the amendment?

An amendment to the way the service is clinically delivered under the existing item(s)

Justification for amendment:

The amendment is to accommodate the use of PENS, The item number 39129 has an explanatory note TN.8.241 which specifically excludes the use of PENS. An alteration to the explanatory note will be required. There is no necessity to change the item number itself.

Relevant MBS items

Please select any relevant MBS items:

| MBS item number | Selected reason type |
|-----------------|---|
| 39129 | Expansion or amendment to existing item |

What is the type of service or health technology?

Therapeutic

Application PICO set: PENS therapy for chronic peripheral neuropathic pain

Supporting documentation

| Document type | Document file name |
|-------------------------------|--|
| Application PICO set document | MSAC application 1739 – PICO Set - PENS therapy for chronic peripheral neuropathic pain.docx |
| Reference list | <i>Refer to Application PICO set document</i> |

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.

Select the most applicable medical condition terminology (SNOMED CT):

Peripheral neuropathic pain

Intervention

Name of the proposed health technology:

Percutaneous Electrical Nerve Stimulation (PENS) therapy

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 |
|---|-----------------|
| MBS Item: 39134 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. | MBS |

| Comparator name | Comparator type |
|---|-----------------|
| <p>In the absence of PENS therapy, implantation of a permanent device incorporatind leads and a pulse generator would be an option for these patients.</p> <p>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</p> | |
| <p>MBS Item: 39138</p> <p>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.</p> <p>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.</p> <p>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. As the therapy is adopted, it is anticipated that a greater proportion of those receiving permanent implants may use PENS therapy instead</p> | MBS |
| <p>MBS Item: 2806</p> <p>A consultation with a consultant pain physician to provide pain management for chronic neuropathic pain</p> <p>In the absence of PENS, a patient would be managed by a pain physician using other methods of pain management</p> | MBS |

Outcomes

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

Outcome 1

Outcome type: Health benefits

Outcome name: Quality of Life

Outcome description: The intervention is not a test

Outcome 2

Outcome type: Health benefits

Outcome name: Pain reduction

Outcome description: The intervention is not a test

Outcome 3

Outcome type: Resources

Outcome name: Reduction in narcotic medication

Outcome description: Reduced use of narcotic medication due to pain reduction

Outcome 4

Outcome type: Resources

Outcome name: Reduction in implantation of neurostimulators

Outcome description: Reduction in use of permanent peripheral 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 peripheral neurostimulator

Proposed MBS items

Please provide at least one proposed item with their descriptor and associated costs, for each Population / Intervention: (repeat the fields highlighted below for each proposed item provided)

| | |
|---|---|
| Proposed item | BBBBB |
| 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 cannot be estimated with any certainty. The amount has been assumed to be \$1000 but may be more or less than this amount. |

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

At present the service is not funded through the MBS and therefore is not covered by private health insurance. The service when delivered must be funded by patients.

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)?

Non-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.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

There is little published information about the prevalence of patients who report chronic neuropathic pain in Australian general practice. Pain data is commonly reported as a total population suffering from 'chronic pain' (grouped as neuropathic or nociceptive [non-neuropathic, musculoskeletal]).

Pan et al. (2016) undertook a study of 97 GPs between February and March 2015. Of the 2848 patients sampled, 25% (n = 722) reported having chronic pain over the preceding six months. One-fifth of these patients (n = 147; 5.2% of the total patients sampled) described chronic neuropathic pain (alone or in combination with nociceptive pain).

We can extrapolate from this that approximately 20% of total chronic pain patients (722) have neuropathic pain. The AIHW 'Chronic Pain in Australia' (2020) report found approximately 19% or 1.6 million Australians aged over 45 reported having chronic pain. It can be estimated that of these 320,000 patients are suffering from chronic neuropathic pain. Please see attached TABLE 1: 'Distribution of chronic pain' and TABLE 2: 'Moderate or severe pain lasting longer than 6 months in people aged 45 and over.

The average numbers of probes sold per year in Australia is between 1000 and 2000 per year (Algotec Sales Data).

In Hamza et al. (2000) patients received treatment for 3 weeks (3 times per week). Each treatment uses between 1 or 2 probes. In this study patients would have required approximately 9 - 15 probes.

The population who could benefit from PENS therapy in Australia is approximately 320,000 neuropathic pain patients.

PENS is an alternative treatment to usual medical management. There is a potential population of 320,000 neuropathic pain patients who are looking for effective pain management.

In practice only a fraction of these patients would receive PENS therapy. As noted above, approximately 1500 Probes are sold in Australia each year. Typically only one Probe is used per procedure unlike the earlier use described in Hamza et al. However, the same patient may typically receive PENS therapy two or three times a year. The frequency may be slightly more than this or significantly less. Therefore an accurate estimate of the number of patients receiving the therapy each year cannot be made.

A more useful way of calculating the utilisation is to look at the utilisation of the item number 39138 before it was modified in March this year and the utilisation of the newly created 39129 (which excludes the use of PENS therapy) and compare it with the utilisation of 39138 prior to the change. The difference is likely to represent the utilisation of PENS therapy.

In Quarter 1 of financial year 2021/22, 39138 was claimed 695 times. In Quarter of financial year 2022/23, 39138 was claimed 314 times and 39129 was claimed 22 times for a total of 226 times. The difference in the number of claims between Q1 2021/22 and Q1 2022/23 is 369. The annual utilisation is likely to be approximately 1476 which equates to the annual sales of PENS therapy Probes.

The percentage uptake is calculated as a percentage of the utilisation of 39138 prior to the alteration of the item number. It is not anticipated that the utilisation of PENS therapy will increase rapidly, but rather at an incremental rate based on past growth.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

47.00

Year 2 estimated uptake (%):

48.50

Year 3 estimated uptake (%):

50.00

Year 4 estimated uptake (%):

51.00

Estimate the number of patients who will utilise the proposed technology for the first full year:

590

Optionally, provide details:

As noted above, PENS therapy patients are likely to receive the service between 2 and 3 times per year. To calculate the number of individual patients, the annual utilisation of 1476 calculated above has been divided by 2.5 to estimate the number of individual patients in the first full year.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Over a number of years - this is variable.

Optionally, provide details:

Patients will receive PENS at variable intervals as noted. This will be dependent upon how long pain relief is sustained.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

1 to 3 times a year.

Optionally, provide details:

As noted above, PENS therapy is typically delivered 2- 3 times a year.

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

Neuromodulation Society of Australian and New Zealand

Faculty of Pain Medicine

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:

Neuromodulation Society of Australian and New Zealand

Faculty of Pain Medicine

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

Number of organisations listed: 1

Pain Australia

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

There are no other additional manufacturers of the technology in Australia

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TPG)?

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG ID's:

| ARTG ID | ARTG name |
|----------------|--|
| 219979 | Probe, stimulator |
| 226115 | NeuroStimulator PENS therapy® Device - Analgesic PENS system |

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes