MSAC application 1712.1

Level 2 sleep studies for the diagnosis and management of sleep disordered breathing in children and adolescents

Application for MBS eligible service or health technology

HPP Application number:

HPP200279

Application title:

Level 2 sleep studies for the diagnosis and management of sleep disordered breathing in children and adolescents

Submitting organisation:

AUSTRALASIAN SLEEP ASSOCIATION

Submitting organisation ABN:

51138032014

Application description

Succinct description of the medical condition/s:

Sleep disordered breathing is common in children, with obstructive sleep apnoea the most prevalent. Obstructive sleep apnoea is a partial or complete closing of the airway during sleep that results in lower oxygen levels within the body, snoring, daytime sleepiness and other health problems. Potential causes of sleep disordered breathing in children include enlarged adenoids and tonsils, obesity, reduced muscle tone of the airway and abnormalities of airway shape or size.

Succinct description of the service or health technology:

Level 2 polysomnography is the measurement of sleep in the same way as polysomnography undertaken in an overnight sleep study in a sleep laboratory. However, the study is undertaken at home or another location that is not a sleep laboratory and there is not continuous monitoring of the signals by a sleep technician as occurs in laboratory sleep study. Instead, signals are recorded overnight and data is downloaded and analysed after the sleep study.

Application contact details

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

Applicant

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

Organisation

Applicant organisation name:

AUSTRALASIAN SLEEP ASSOCIATION

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 Prescribed List?

No

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

New

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology: *(if investigative)*

Other

PICO sets

Application PICO sets:

PICO set name
Children and adolescents who have been determined by a qualified sleep medicine practitioner to require polysomnography (PSG) to evaluate suspected obstructive sleep apnoea (OSA)

Population

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

- Medically uncomplicated children at least 3yrs of age but less than 18yrs.
- Suspected diagnosis obstructive sleep apnoea (OSA).
- Minor associated medical conditions assessed as appropriate for home studies

by the sleep physician. For example asthma, mild epilepsy, mild autism, obesity, Pierre-Robin sequence ± cleft palate, Treacher Collins syndrome, neurofibromatosis, and multiple sclerosis.

Intervention

Name of the proposed health technology:

Level 2 ambulatory polysomnography

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:

Level 1 attended polysomnography (MBS item 12210 for children or 12213 for adolescents.)

Outcomes

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

The addition of a Level 2 study as an option will service the current group of children referred for level 1 PSG (comparator) by facilitating more timely diagnostic testing and reducing time to treatment. The outcome measured therefore will be the delay to receiving a definitive diagnosis of (or exclusion of the diagnosis of) OSA.
For children and adolescents who receive the proposed Level 2 study, the change in management means that the impacts of untreated OSA are reduced by reducing the time a patient experiences untreated OSA. Treatment of OSA has been shown to improve child behaviour and quality of life and may help to reduce the risk of later cardiovascular and metabolic complications.

Proposed MBS items

Please provide at least one proposed item with their descriptor and associated costs, for each population / intervention:

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

Category number:

2

Category description:

Diagnostic Procedures and Investigations

Proposed item descriptor:

Overnight investigation of sleep for at least 8 hours, for a patient aged at least 3 years but less than 12 years to confirm diagnosis of obstructive sleep apnoea, if:
(a) (i) the patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner; and
(ii) following professional attendance on the patient (either face to face or by video conference) by a qualified paediatric sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea and that an out-of-laboratory setting is appropriate for the sleep study; and
(b) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 7 channels that include (i) to (vii) of the following measures:
(i) airflow;
(ii) EEG;
(iii) EMG;
(iv) EOG;
(v) ECG or heart rate;
(vi) oxygen saturation;
(vii) respiratory effort;

(c) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner; and
(d) either:
(i) the equipment is applied to the patient by a sleep technician; or
(ii) if this is not possible – the reason it is not possible for the paediatric sleep laboratory technician to apply the equipment to the patient is documented and a parent or caregiver is given instructions on how to apply the equipment under the supervision of the sleep laboratory.
(e) written instructions are given to parent/caregiver to monitor the patient overnight and a phone contact or data link to the paediatric sleep laboratory to enable trouble shooting

overnight if required; and
(f) polygraphic records are:
(i) analysed for assessment of sleep stage, arousals, respiratory events, and cardiac abnormalities using manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
(ii) stored for interpretation and preparation of a report; and
(g) interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist with personal direct review of raw data from the original recording of polygraphic data from the patient; and
(h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Proposed MBS fee:

$487.08

Indicate the overall cost per patient of providing the proposed health technology:

$487.08

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

Estimates provided

- 2 hrs of sleep professional time setup study and ensure data recording – parents/caregiver aware how to trouble shoot $66/hr (incl on costs) x2 = 132.08
- Consumables = $75
- 2hrs: Download, analysis, data integrity = $70/hr= $140
- 60 mins scoring/interpretation and report from paediatric sleep medicine specialist approx. average $140 (inc on costs)

Proposed item:

BBBBB

MBS item number (where used as a template for the proposed item):

Category number:

2

Category description:

Diagnostic Procedures and Investigations

Proposed item descriptor:

Overnight investigation of sleep for at least 8 hours, for a patient aged at least 13 years but less than 18 years to confirm diagnosis of obstructive sleep apnoea, if:
(a) (i) the patient has been referred by a medical practitioner to a qualified paediatric or

adult sleep medicine practitioner; and
(ii) following professional attendance on the patient (either face to face or by video conference) by a qualified paediatric or adult sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea and that an out-of-laboratory setting is appropriate for the sleep study; and
(b) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 7 channels that include (i) to (vii) of the following measures:
(i) airflow;
(ii) EEG;
(iii) EMG;
(iv) EOG;
(v) ECG or heart rate;
(vi) oxygen saturation;
(vii) respiratory effort;
(c) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner; and
(d) either:
(i) the equipment is applied to the patient by a sleep technologist; or
(ii) if this is not possible – the reason it is not possible for the paediatric or adult sleep laboratory professional to apply the equipment to the patient is documented and a parent or caregiver is given instructions on how to apply the equipment by the sleep laboratory.
(e) written instructions are given to parent/caregiver to monitor the patient overnight and a phone contact or data link to the paediatric or adult sleep laboratory to enable trouble shooting overnight if required; and
(f) polygraphic records are:
(i) analysed for assessment of sleep stage, arousals, respiratory events, and cardiac abnormalities using manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
(ii) stored for interpretation and preparation of a report; and
(g) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine specialist with personal direct review of raw data from the original recording of polygraphic data from the patient; and
(h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Proposed MBS fee:

$454.00

Indicate the overall cost per patient of providing the proposed health technology:

$454.00

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

Estimates provided

- 1.5 hr of sleep professional time setup study and ensure data recording – parents/caregiver aware how to trouble shoot $66/hr (incl on costs) x1.5 =$99
- Consumables = $75
- 2hrs: Download, analysis, data integrity = $70/hr= $140
- 60 mins scoring/interpretation and report from paediatric sleep medicine specialist approx. average $140 (inc on costs)

Proposed item:

CCCCC

MBS item number (where used as a template for the proposed item):

Category number:

2 Rural and Remote (MM 3-7)

Category description:

Diagnostic Procedures and Investigations

Proposed item descriptor:

Overnight investigation of sleep for at least 8 hours, for a patient aged at least 3 years but less than 12 years to confirm diagnosis of obstructive sleep apnoea, if:
(a) (i) the patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner; and
(ii) following professional attendance on the patient (either face to face or by video conference) by a qualified paediatric sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea and that an out-of-laboratory setting is appropriate for the sleep study; and
(b) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 7 channels that include (i) to (vii) of the following measures:
(i) airflow;
(ii) EEG;
(iii) EMG;
(iv) EOG;
(v) ECG or heart rate;
(vi) oxygen saturation;
(vii) respiratory effort;

(c) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner; and
(d) either:
(i) the equipment is applied to the patient by a sleep technician; or
(ii) if this is not possible – the reason it is not possible for the paediatric sleep laboratory technician to apply the equipment to the patient is documented and a parent or caregiver is given instructions on how to apply the equipment under the supervision of the sleep

laboratory.
(e) written instructions are given to parent/caregiver to monitor the patient overnight and a phone contact or data link to the paediatric sleep laboratory to enable trouble shooting overnight if required; and
(f) polygraphic records are:
(i) analysed for assessment of sleep stage, arousals, respiratory events, and cardiac abnormalities using manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
(ii) stored for interpretation and preparation of a report; and
(g) interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist with personal direct review of raw data from the original recording of polygraphic data from the patient; and
(h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Proposed MBS fee:

$587.08

Indicate the overall cost per patient of providing the proposed health technology:

$587.08

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

Estimates provided:

- 2 hrs of sleep professional time setup study and ensure data recording – parents/caregiver aware how to trouble shoot $66/hr (incl on costs) x2 = 132.08
- Consumables = $75
- 2hrs: Download, analysis, data integrity = $70/hr= $140
- 60 mins scoring/interpretation and report from paediatric sleep medicine specialist approx. average $140 (inc on costs)
- Equipment delivery/postage costs= $100

Proposed item:

DDDDD

MBS item number (where used as a template for the proposed item):

Category number:

2 Rural and Remote MM 3-7

Category description:

Diagnostic Procedures and Investigations

Proposed item descriptor:

Overnight investigation of sleep for at least 8 hours, for a patient aged at least 13 years but less than 18 years to confirm diagnosis of obstructive sleep apnoea, if:
(a) (i) the patient has been referred by a medical practitioner to a qualified paediatric or adult sleep medicine practitioner; and
(ii) following professional attendance on the patient (either face to face or by video conference) by a qualified paediatric or adult sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea and that an out-of-laboratory setting is appropriate for the sleep study; and
(b) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 7 channels that include (i) to (vii) of the following measures:
(i) airflow;
(ii) EEG;
(iii) EMG;
(iv) EOG;
(v) ECG or heart rate;
(vi) oxygen saturation;
(vii) respiratory effort;
(c) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner; and
(d) either:
(i) the equipment is applied to the patient by a sleep technologist; or
(ii) if this is not possible – the reason it is not possible for the paediatric or adult sleep laboratory professional to apply the equipment to the patient is documented and a parent or caregiver is given instructions on how to apply the equipment by the sleep laboratory.
(e) written instructions are given to parent/caregiver to monitor the patient overnight and a phone contact or data link to the paediatric or adult sleep laboratory to enable trouble shooting overnight if required; and
(f) polygraphic records are:
(i) analysed for assessment of sleep stage, arousals, respiratory events, and cardiac abnormalities using manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
(ii) stored for interpretation and preparation of a report; and
(g) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine specialist with personal direct review of raw data from the original recording of polygraphic data from the patient; and
(h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Proposed MBS fee:

$554.00

Indicate the overall cost per patient of providing the proposed health technology:

$554.00

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

Estimates provided

- 1.5 hr of sleep professional time setup study and ensure data recording – parents/caregiver aware how to trouble shoot $66/hr (incl on costs) x1.5 =$99
- Consumables = $75
- 2hrs: Download, analysis, data integrity = $70/hr= $140
- 60 mins scoring/interpretation and report from paediatric sleep medicine specialist approx. average $140 (inc on costs)
- Equipment delivery/postage costs= $100

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

Self-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:

The proposed technology is claimed to be non-inferior based on the available evidence in current literature. The level 2 test will be utilised for children who have been referred to sleep physicians for a suspicion of obstructive sleep apnoea. Availability of level 2 studies is expected to reduce waiting times in those needing investigation for OSA and who meet the proposed criteria.

Estimated utilisation

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

Approximately 30% of current waitlisted children would be eligible for an ambulatory sleep study.

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

Year 1 estimated uptake (%):

30

Year 2 estimated uptake (%):

30

Year 3 estimated uptake (%):

30

Year 4 estimated uptake (%):

30

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

Approximately 30% of waitlisted patients

Will the technology be needed more than once per patient?

No, once only

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entity who provides the health technology/service:

Australia and New Zealand Sleep Science Association Ltd

Entity who requests the health technology/service

Australasian Sleep Association

Entity who may be impacted by the health technology/service

Australasian Sleep Association

Australia and New Zealand Sleep Science Association Ltd

Patient and consumer advocacy organisations relevant to the proposed service/health technology

The Sleep Health Foundation

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 (TGA)? *(if 'Yes' above)*

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 IDs:

ARTG ID	ARTG name
157479	Pulse Co-oximeter
198298	Sleep assessment device
232041	Nox A1 and T3 Systems - Polysomnography analyser
343713	Somnomedics PSG - Sleep assessment device

Is the therapeutic good classified by the TGA as for Research Use Only (RUO)?

No