MSAC Application 1712.1

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

PICO Set

Population

Describe the population in which the proposed health technology is intended to be used:
The proposed population is children and adolescents who have been determined by a qualified sleep medicine practitioner to require polysomnography (PSG) to evaluate suspected obstructive sleep apnoea (OSA). Candidates must be deemed appropriate for an out-of-laboratory setting by the specialist sleep physician who requests the study.

Included:

- 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.

Excluded:

- High risk children, where high-risk is defined as being at risk of hypoventilation or with complex co-morbidities as assessed by the sleep physician as being inappropriate for home study (e.g. complex heart disease).
- children suspected of sleep movement disorders, suspected nocturnal seizures, atypical parasomnias, hypersomnia and narcolepsy, or
- children initiating respiratory support.

The proposed intervention is a Level 2 PSG study for diagnosis of OSA in children aged 3-18 years.

Proposed MBS items include:

(i) level 2 PSG for patients at least 3yrs but less than 12 yrs
(ii) level 2 PSG for patients at least 12yrs but less than 18yrs
(iii) level 2 PSG for patients at least 3 years but less than 12 years living rural/remote requiring telehealth support for PSG
(iv) level 2 PSG for patients at least 12yrs but less than 18yrs living rural/remote requiring telehealth support for PSG.

The Level 2 PSG study is proposed as a replacement test for Level 1 PSG.

Definition of Rural and Remote:

The Modified Monash Model is suggested to define whether a location is metropolitan, rural, remote or very remote in keeping with use in other item numbers. MM1 is a major city and MM7 is very remote. The proposed item numbers for rural/remote are suggested for MM3-MM7 (approximately 30% of the Australian population).

Specify any characteristics of patients with, or suspected of having, the medical condition, who are proposed to be eligible for the proposed health technology, describing how a patient would be investigated, managed and referred within the Australian healthcare system in the lead up to being considered eligible for the technology:
A child or adolescent (ages 0-18yrs) is referred to a paediatric sleep physician. Adolescents aged at least 12yrs but less than 18yrs may be evaluated by an adult sleep physician.

Suspected obstructive sleep apnoea is based on symptoms such as snoring, mouth breathing, gasps and pauses in breathing, daytime tiredness and/or daytime dysfunction (such as learning

and behaviour problems). This would be accompanied by physical examination for signs such as enlarged tonsils, nose and/or soft palate abnormalities, or obesity.

The sleep physician assesses the patient and determines that OSA should be investigated with an overnight sleep study. If the child is at least 3yrs of age without additional complicating medical comorbidities (see above inclusion and exclusion criteria) factors and their parent/carer is willing and able to supervise the home sleep study a level 2 study could be performed. Few parents decline to supervise the home study; Griffiths et al reported that 91% of parents reported that home studies were more convenient than coming to the hospital.

The sleep physician arranges for a Level 2 sleep study to be conducted.

In contrast to adult populations, there are no validated questionnaires that can evaluate high risk for OSA in children. See "Differences between adult and paediatric studies" below.

Provide a rationale for the specifics of the eligible population:

1. A clear clinical need:

Paediatric Sleep Medicine is a "young" medical specialty, with the first sleep units for children only established in the 1990's. Australia is a leader in the field internationally, due to the local development of nasal CPAP as a therapy for adults, and its subsequent introduction for use in children.

Developments in understanding sleep disorders mean that there is increased recognition of the disease, integration of the clinical service into tertiary hospitals clinical specialties, and referrals to sleep medicine are now received frequently from most of the other subspecialties, as well as from primary care. The complexity of laboratory testing (Level 1 PSG) with space, and cost limitations leading to a cap on laboratory capacity for testing has led to progressive growth in waiting lists for sleep studies for children. The consequences of undiagnosed and therefore untreated OSA in children include neurocognitive problems, behavioural problems, poor school performance, growth disturbances and increased cardiovascular risks (Gozal et al 2004; Katz and D'Ambrosio 2008; Baker-Smith et al 2021). Unidentified and untreated OSA can lead to significant impairment of a child's health, opportunities, and quality of life.

Clinicians have attempted to redress these issues by implementing screening measures, particularly oximetry, but this does not always negate the need for level 1 diagnostic study.

2. Addressing waiting times:

The major delay in obtaining sleep studies is the delay between seeing a specialist sleep physician and obtaining the level 1 PSG study. While the waiting times for clinic appointments across tertiary paediatric hospitals in Australia average 3-6 months, waiting times for sleep studies <u>after</u> seeing the specialist in these same centres averages 12 months.

3. Equity and access barriers and how these can be overcome:

The requirement for tertiary hospital paediatrics to focus on the needs of children with medically complex conditions also means that children who are perceived to be "otherwise medically uncomplicated" often experience significant delays in access and undergo the longest wait times for a sleep study. In other paediatric sub-specialities this problem is overcome by redirecting medically uncomplicated patients to other local community specialists who can provide care and the tertiary hospital services will not accept referrals and refuse to evaluate this sub-group of children. However, in paediatric sleep medicine there is no ability to defer these uncomplicated patients as no alternative services exist. Paediatric sleep labs are almost exclusively located in tertiary centres located in cities. This group of medically uncomplicated children are therefore the

ideal group who can be diagnosed by a level 2 home PSG which would improve equity and facilitate timelier diagnosis and ultimately definitive treatment.

From the patient perspective, particular barriers to obtaining a sleep study for children are encountered by children in rural and remote communities. The difficulty for this group is the lack of paediatric sleep services local to their residence. Telehealth consultations have increased the ability to undertake an initial sleep consultation, but if a diagnostic PSG is warranted this requires a visit to the tertiary hospital. A model that facilitates a supported level 2 PSG would help to increase equity of service for this group but needs to account for the additional cost to support equipment delivery to rural/remote locations in Australia. Specific item numbers for rural/remote locations are therefore proposed.

Under current clinical and Medicare reimbursed pathways, the whole population of eligible children would be referred for a Level 1 (in-laboratory) PSG to evaluate the presence and severity of obstructive sleep apnoea.

Children at least 3yrs of age may be suitable for a Level 2 home PSG rather than a Level 1 PSG to assess their suspected OSA.

The waiting time for children to see sleep physicians would not be affected by the introduction of the new item numbers. However, the waiting time to the sleep study would be reduced. Sleep laboratories have fixed capacity for sleep study numbers (detailed in Table 1). The capacity to undertake additional home sleep studies would be limited by staffing capacity for set-up and reporting, and equipment availability, but would not be capped by physical bed spaces in the same way as the laboratory level 1 sleep studies. This pathway would seek to target a group of children currently waiting longest for level 1 PSG assessment

Some clinicians may establish a service providing ONLY level 2 studies, which would avoid the need for a physical location with bed spaces for the supervised in-laboratory studies. This would further reduce the bottleneck for PSG assessment and help ensure equity of access for those who do not reside near a tertiary centre.

Children under 3 years or with medical complexity, such as multiple comorbidities, complex congenital heart disease and epilepsy syndromes, should continue to be assessed with a Level 1 PSG in a paediatric sleep laboratory to ensure their safety and data accuracy. Children and adolescents with a high suspicion of hypoventilation (alone or in addition to) OSA must also be investigated with a Level 1 study in an attended sleep laboratory to ensure appropriate monitoring (e.g. transcutaneous carbon dioxide monitoring) is included in their study.

Differences between adult and paediatric studies

1. Determination of need for testing:

Unattended studies are currently available for adults (Item 12250). Criteria for testing in adults is either determined by a qualified sleep and/or respiratory physician within a medical consultation, or via validated questionnaires (STOP-Bang score of 3 or more, OSA 50 score of 5 or more, or a high-risk score on the Berlin Questionnaire, and an Epworth Sleepiness Scale score of 8 or more). However, these questionnaire screening options are <u>not</u> suitable for children and no other questionnaire screening tools have proven sufficiently reliable to be used in their place. Therefore, suitability for testing can only be determined by a (paediatric) sleep and/or respiratory physician within the context of a medical consultation. This means there is no "direct to testing pathway" as there is for adults. The specific requirement for review by a paediatric sleep physician is to allow them to assess the child's suitability for the unattended study <u>and</u> to evaluate the parents' ability and willingness to supervise the study themselves. This need for consultation would not create a barrier to testing with Level 2 PSG, as this is required for the current pathway of Level 1 PSG

testing and the major delay to diagnosis and treatment of suspected OSA is related to the waiting times for Level 1 PSG (see Table 1 and text above).

2. Time taken for patient set up and analysis for polysomnography:

Application of leads for children having sleep studies takes longer than for adults, as children are frequently unable to fully cooperate with the procedure. Especially for children at least 3yrs of age but less than 12 years of age, there may also need to be brief breaks so that they can tolerate the procedure without undue distress. The longer time for set-up accounts for the increased cost of the test in children. There is also no reliable option for automated scoring in children at this stage, so scoring must be completed manually by a suitably-experienced technician.

3. Assistance required for patient set up for polysomnography:

With respect to equipment application, for adults the default is for a sleep technician to apply the leads. However, where equipment cannot be applied by a sleep technician the patient can be given instructions on how to apply the equipment themselves, supported by written and/or video instructions. This allows for easy access for adults to community-based testing models such as in pharmacies, including in rural/remote regions. In contrast, for paediatrics, where applying leads can be more difficult due to their frequent inability to fully cooperate with the procedure, it is more important to have a sleep technician available to provide support. In this proposal we have modified the requirement for equipment application to allow for a sleep technician to be available via telehealth to guide the placement of leads and troubleshoot as required. This also is the reason why separate item numbers are proposed for rural/remote patients in paediatrics, whereas this has not been deemed necessary for the adult item number.

Are there any prerequisite tests?
No

Are the prerequisite tests MBS funded?
N/A

Provide details to fund the prerequisite tests:
N/A

Intervention

Name of the proposed health technology:
Level 2 ambulatory polysomnography

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

1) Child or adolescent aged 3-18 years with suspected OSA and referred to a paediatric sleep physician (if less than 12 years) or a paediatric or adult sleep physician (at least 12yrs of age but under18 years).
2) Sleep physician assesses the child and determines a sleep study is required to diagnose OSA, there is no medical complexity that requires a Level 1 study, and there is low likelihood of other sleep disorders being present.
3) Sleep physician determines that the child is suitable for a Level 2 study and their parent/carer is willing and able to manage the sleep study process at home or an alternative location.
4) On the evening of the sleep study, either:

   a. the equipment is applied to the child by a sleep technician or
   b. the child attends a sleep laboratory for the necessary equipment set up and instructions are provided to the parent/carer on operation of the equipment overnight or
   c. If either of these options is not possible (i.e. unable to attend to have set up or collect equipment due to e.g. geographic location), the reason it is not possible for the sleep technician to apply the equipment to the patient is documented, and the patient's parent is remotely given instructions on how to apply the equipment by a sleep technician with support from written and/or video instructions.*

5) A paediatric sleep technician is on call for the parent/carer overnight to help trouble shoot any problems with the equipment.
6) In the morning the parent/carer removes the equipment, and it is returned to the sleep laboratory, either in person or via return postage if it was delivered prior to testing.
7) Data is downloaded from the equipment. Polygraphic records are:
   (i) analysed (for assessment of sleep stage, arousals, respiratory events and cardiac abnormalities) with manual scoring (automated scoring is not currently accurate in paediatric practice)
   (ii) stored for interpretation and preparation of a report; and
8) Interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine practitioner with personal direct review of raw data from the original recording of polygraphic data from the patient.

* Note that for remote/rural patients, the treating sleep service would need to arrange postage of equipment to the family and then provide telehealth assistance for the set-up, therefore this additional expense will need to be covered. Additional item numbers are proposed with a delivery surcharge included in the cost to account for this (an average cost acknowledging this would be more/less for some areas).

Identify how the proposed technology achieves the intended patient outcomes:
Level 2 PSG diagnosis of OSA via a minimum of at least these seven measures:

(i) airflow
(ii) EEG
(iii) EMG
(iv) EOG
(v) ECG or heart rate
(vi) oxygen saturation
(vii) respiratory effort.

Together these measures are sufficient to diagnose or exclude OSA, resulting in the child proceeding to appropriate treatment. Treatment may be conservative medical management, ENT surgery or CPAP/NIV therapy.

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?
No

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

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):
Yes

Provide details and explain:
A maximum of three Level 2 sleep studies to be delivered to any one patient in any 12-month period.

If applicable, advise which health professionals will be needed to provide the proposed health technology:
A sleep service will need to supply the equipment for Level 2 polysomnography.

The equipment will be applied to the child by a sleep technician or the parent/carer under the supervision of a sleep technician.

A sleep technician will be available overnight to the parent/carer to help trouble shoot any issues.

Data will be analysed by a paediatric sleep technician as automated scoring of data is not adequate in paediatric populations.

The sleep study will be reported by a qualified sleep physician following review of the raw data.

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

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:
The referral for Level 2 polysomnography must be made by a paediatric sleep physician (3-12 years) **or for adolescents (at least 12yrs of age but under 18 years), a paediatric or an adult sleep physician may recommend and evaluate the study**. This is so the patient is appropriately assessed and any potential risk factors are considered when making the decision to undertake a Level 2 study.

The application is for level 2 to replace a proportion of level 1 studies, without changing the clinical pathway currently required to undergo evaluation for a PSG (for paediatrics all children see a sleep physician prior to being waitlisted for PSG). This will mean there are no significant changes to referral patterns to paediatric sleep physicians. Waiting times will be reduced by reducing the time after seeing the sleep physician to the time of the diagnostic study by providing access to level 2 PSG. The ability of adult sleep physicians to assess and refer adolescents (at least 12yrs of age but under 18yrs) for a sleep study offers another mechanism for reducing the current wait times between physician assessment and performance of a level 1 in-laboratory study and helps ensure that there will not be any inadvertent bottleneck to see a referring physician prior to testing.

Oversight for testing is provided by the fact that:

1. Level 2 studies need to be provided by a paediatric sleep service or adult service for adolescents at least 12yrs of age but less than 18yrs.

2. The supervising/billing physician takes responsibility for the appropriate performance of the test.

3. The test is performed according to "current professional guidelines" - this is already embedded in the Level 1 item numbers for paediatric and adult sleep studies

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:
The study must be requested by a sleep physician who is qualified to assess and report on sleep studies in the relevant age range (paediatric for 3-12 years and paediatric or adult sleep physician for children aged at least 12yrs of age but under-18 years). Specific skills and training are required to analyse paediatric sleep study data because automatic analysis is unreliable in paediatric patients.

Indicate the proposed setting(s) in which the proposed health technology will be delivered:
☐ 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)

The proposed diagnostic test will be undertaken at a suitable location that is not an attended overnight sleep laboratory. Most commonly this will be at the child's home but it could potentially be undertaken in other non-laboratory settings.

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

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 healthcare system). This includes identifying healthcare resources that are needed to be delivered at the same time as the comparator service:

The comparator Level 2 PSG study (diagnostic) is a diagnostic Level 1 PSG study under MBS item 12210 for children or 12213 for adolescents.

List any existing MBS item numbers that are relevant for the nominated comparators:

MBS item 12210 for children or 12213 for adolescents

Provide a rationale for why this is a comparator:
Adults currently have access to either a Level 1 or Level 2 PSG rebated under the MBS. This application seeks to allow children and adolescents **equivalent access** to lower-cost, more accessible and more convenient out-of-laboratory diagnostic testing. In the proposed population, two studies (Cielo et al. 2023; Withers et al. 2022) reported equivalent **test accuracy** of Level 2 PSG studies compared to Level 1 PSG studies. No difference in **test failures** was reported between Level 1 PSG (range 0-5%) and Level 2 PSG (range 0-7%) in the two cross-sectional accuracy studies. In addition, five single-arm studies reported initial Level 2 test failure rates ranging from 9-19% (Goodwin et al. 2001; Griffiths et al. 2022; Ioan et al. 2020; Marcus et al. 2014; Russo 2021). One included study, Griffiths et al. (2022), an Australian single-arm, single-centre, retrospective audit of Level 2 PSG studies (diagnostic), reported **no adverse events** during the study period.

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 all).
☐ Full (subjects who receive the proposed intervention will not receive the comparator)

Outline and explain the extent to which the current comparator is expected to be substituted:
The current comparator will be substituted if a child is:

- suspected of having OSA,
- at least 3 years of age,
- has no major medical comorbidities (e.g. hypoventilation, cardiac disease, developmental disorders anticipated to affect tolerance for the polysomnography), and
- parent/carer is willing to supervise the overnight sleep study at home.

The average overall wait time across the public paediatric sleep services in Australia is around 12-18 months for a PSG, from the time that the child is evaluated by their sleep physician. All referred patients see a sleep physician prior to being waitlisted for a level 1 study and prioritisation for PSG is determined by the sleep physician. Children deemed to require urgent PSG are accommodated as necessary within category 1 wait times (30 days).

Sleep laboratories have a fixed maximum capacity for studies based on bed numbers, and funding for staff. For example, the 3 laboratories represented by members of the committee:

- Sydney Children's Hospital Westmead – 1000 (20 studies per week -4 beds, 5 nights maximum)
- Royal Children's Hospital – 552 (12 studies per week for 46 weeks per year)
- Queensland Children's Hospital – 1380 (30 studies per week -6 beds, 5 nights maximum for 46 weeks per year)

At the same time, the number of requests for Level 1 studies received means that the waiting lists are currently steadily increasing. For example:

- Queensland Children's Hospital received 1425 requests for sleep studies in 2023 which exceeds current capacity by 5% (2024 figures not yet available)
- Royal Children's Hospital received 632 requests for sleep studies in 2024 which exceeds current capacity by 14%.

Note: This does not account for urgent inpatient requests

Data from current sleep laboratory waiting lists for Level 1 sleep studies estimates that around 30% of children and adolescents would be suitable for a Level 2 sleep study once funded. We estimate this to be the expected uptake rate for the proposed item numbers. We expect the demand for this service to be the same in metropolitan and rural/remote areas and therefore propose that ABS data on population proportions in the <18yr age group living rural and remote (approximately 30% of the Australian population) are used to estimate potential uptake of the different item numbers for the stated geographical locations.

Table 2. On the specific dates listed below, details from the waitlists for four paediatric sleep laboratories were as follows (note that these were representative samples and not all children on all of the waiting lists were evaluated).

Paediatric sleep laboratory	Date of data interrogation	Total number of children on waitlist	Number meeting proposed criteria for Level 2 study	% of waitlist suitable for Level 2
Sydney Children's Hospital Westmead	19 November 2024	266	97	36.5%
Queensland Children's Hospital	22 November 2024	200	75	37.5%
Monash Children's Hospital	27 November 2024	463	150	32.3%
Sydney Adventist Hospital (Private)	November 2024 – actual case load	0 on waitlist, 49 patients studied during November	15	30.6% of actual case load

Outcomes

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):

☒ Health benefits
☐ Health harms
☒ Resources
☐ Value of knowing

Outcome description – 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 [1-6]. Proposed

Level 2 sleep studies for the diagnosis and management of sleep disordered breathing in children and adolescents – PICO Set 1

MBS items include (i) level 2 PSG for patients at least 3yrs but less than 12 yrs, (ii) level 2 PSG for patients at least 12yrs but less than 18yrs, (iii) level 2 PSG for patients at least 3 years but less than 12 years living rural/remote (MMM 3-7) requiring telehealth support for PSG and (iv) level 2 PSG for patients at least 12yrs but less than 18yrs living rural/remote (MMM 3-7) requiring telehealth support for PSG.

How is the technology/service funded at present? (e.g., research funding; State-based funding; self-funded by patients; no funding or payments):
Self-funded by patients

Provide at least one proposed item with their descriptor and associated costs, for each Population/Intervention:

MBS item number (where used as a template for the proposed item)	Specify MBS item number here 12210 and 12250
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 Current paediatric level 1 12210 Fee: $799.60 Benefit 75% =$599.70, 85% =$697.20 (Adult item number:12250 **Fee:** $381.95 **Benefit:** 75% = $286.50 85% = $324.70)	**Fee: $487.08 Benefit 75% = $365.31 85%= $414.02**
Indicate the overall cost per patient of providing the proposed health technology	Insert overall cost per patient amount here 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)
Please specify any anticipated out of pocket expenses	Specify anticipated out of pocket costs here Anticipated out of pocket costs would be travel for collecting equipment as per adult item numbers. If the distance for travel is too great and cannot be resolved and would lead to inequity in service provision the default would be a level 1 in lab test or a separate home PSG item number accounting for the increased costs of equipment delivery and remote support (see below)
Provide any further details and explain	

MBS item number (where used as a template for the proposed item)	Specify MBS item number here 12213 and 12250
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 Current adolescent level 1 12210 Fee: $720.30 Benefit 75% =$540.25, 85% =$617.90 (Adult item number:12250 **Fee:** $381.95 **Benefit:** 75% = $286.50 85% = $324.70)	Insert proposed fee here **Fee: $454.00 Benefit: 75% = $340.50 85% = $385.90**
Indicate the overall cost per patient of providing the proposed health technology	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)
Please specify any anticipated out of pocket expenses	Specify anticipated out of pocket costs here Anticipated out of pocket costs would be travel for collecting equipment as per adult item numbers. If the distance for travel is too great and cannot be resolved and would lead to inequity in service provision the default would be a level 1 in lab test or a separate home PSG item number accounting for the increased costs of equipment delivery and remote support (see below)
Provide any further details and explain	

MBS item number (where used as a template for the proposed item)	Specify MBS item number here 12210 and 12250
Category number	2 Rural and remote (MMM 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 Current paediatric level 1 12210 Fee: $799.60 Benefit 75% =$599.70, 85% =$697.20 (Adult item number:12250 **Fee:** $381.95 **Benefit:** 75% = $286.50 85% = $324.70)	Fee: $587.08 Benefit 75% = $440.31 85%= $499.02
Indicate the overall cost per patient of providing the proposed health technology	Insert overall cost per patient amount here 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
Please specify any anticipated out of pocket expenses	Specify anticipated out of pocket costs here Anticipated out of pocket costs would be travel for collecting equipment as per adult item numbers. If the distance for travel is too great and cannot be resolved and would lead to inequity in service provision the default would be a level 1 in lab test or a separate home PSG item number accounting for the increased costs of equipment delivery and remote support
Provide any further details and explain	Express post Australia post – $35-40 (Australia wide) Courier cost average- $50 (e.g. metro) to $200 (e.g. Brisbane to far north QLD) Weight of level device approx-3-5kg

Level 2 sleep studies for the diagnosis and management of sleep disordered breathing in children and adolescents – PICO Set 1

MBS item number (where used as a template for the proposed item)	Specify MBS item number here 12213 and 12250
Category number	2 Rural and Remote (MMM 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 Current adolescent level 1 12210 Fee: $720.30 Benefit 75% =$540.25, 85% =$617.90 (Adult item number:12250	Insert proposed fee here **Fee: $554.00 Benefit: 75% = $415.50 85% = $470.9**

Fee: $381.95 **Benefit:** 75% = $286.50 85% = $324.70)	
Indicate the overall cost per patient of providing the proposed health technology	Insert overall cost per patient amount here 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
Please specify any anticipated out of pocket expenses	Specify anticipated out of pocket costs here Anticipated out of pocket costs would be travel for collecting equipment as per adult item numbers. If the distance for travel is too great and cannot be resolved and would lead to inequity in service provision the default would be a level 1 in lab test or a separate home PSG item number accounting for the increased costs of equipment delivery and remote support
Provide any further details and explain	Express post Australia post – $35-40 (Australia wide) Courier cost average- $50 (e.g. metro) to $200 (e.g. Brisbane to far north QLD) Weight of level device approx-3-5kg

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:
The patient will be referred to a specialist sleep physician by a medical practitioner for suspected OSA based on history including features such as:

- Frequent snoring (3+ nights / wk), snorting, gasping, choking, and/or
- Affected daytime behaviour – e.g. lack of concentration, inattention, learning problems, daytime sleepiness, mouth breathing, and/or
- Visibly enlarged tonsils, and/or
- Obesity.

The sleep physician will assess the patient. Providing the parent or caregiver is willing and able to support a home sleep study, the sleep physician will refer the patient for a Level 2 sleep study if the patient meets the suitability criteria:

1. the patient is at least 3yrs of age but less than 18yrs, and
2. the patient is not at risk of hypoventilation, and

3. the patient has no other potential sleep disorders such as narcolepsy, parasomnias, restless legs syndrome or complex co-morbidities such as cardiac disease

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:
There is no difference in the clinical management algorithm between the proposed health technology and the comparator apart from the populations accessing each. High complexity patients who do not meet the criteria proposed for Level 2 studies will still need to be able to access Level 1 sleep studies. Access to testing for less complex patients will improve through greater accessibility of Level 2 sleep studies and shorter waiting lists.

USE OF THE HEALTH TECHNOLOGY

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

- a sleep specialist initial consultation
- sleep study equipment owned by a sleep laboratory/service
- a paediatric sleep technician to set up equipment for the study on the patient, or who is available to support the parent/caregiver to do this
- a paediatric sleep technician to be available on call overnight to trouble shoot any issues with the sleep study
- a paediatric sleep technician downloads and analyses sleep study data,
- a paediatric sleep specialist views raw data, interprets and reports the data, and
- a paediatric sleep specialist makes management decisions or refers the patient on (e.g. for ENT surgery) or back to the primary care team, communicating the results to the child's parent/caregiver.

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

- a paediatric sleep specialist initial consultation
- a sleep laboratory/service
- sleep study equipment owned by a sleep laboratory
- a paediatric sleep technician to set up equipment for the study on the patient and monitor the patient continuously overnight
- a paediatric sleep technician to download and analyse sleep study data
- a sleep specialist to view raw data, interpret and report the data, and
- a sleep specialist to make management decisions, or refer the patient on or back to the primary care team, communicating the results to the child's parent/caregiver.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:
The primary difference will be that a Level 2 study does not have continuous in-laboratory monitoring by a sleep technician, which leads to significant cost savings. Provision of on-call support, and technician analysis of the study signals (data) will continue to be required.

A level 2 study is performed "out of laboratory", predominantly – although not exclusively – in the patient's home. The primary caregivers will be involved in the initial set-up of the level 2 study with the support of the sleep technician. This may be using different models, for example:

- child and caregiver attend a laboratory for equipment to be set up
- caregiver attends a laboratory to receive equipment and instructions for application
- equipment is delivered to patient in rural and remote area and set up is supported remotely by a sleep technician (telehealth).

Phone/telehealth support overnight would be provided as required for all of the different models used to support any issues with the Level 2 study equipment.

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:
After a Level 2 study is completed, clinical management will depend on the findings of the diagnostic test.

- If OSA is not found, no further management is required by the sleep physician. A letter is written to communicate negative findings to the referring clinician.
- If OSA is found, a letter is written to communicate findings and proposed management by the sleep physician to the referring clinician. Depending on the findings, management options include onward referral for adenotonsillectomy, conservative medical treatment and monitoring, or initiation of CPAP/NIV.
- If the test fails through insufficient data or is inconclusive, a repeat Level 2 study can be initiated. Depending on the cause of the failure (for example if the caregiver was not able to effectively monitor the home sleep study or is not willing to supervise a repeat test), the sleep physician may decide that a Level 1 study is more likely to deliver a successful result.

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the comparator health technology:
After a Level 1 study is completed, clinical management will depend on the findings of the diagnostic test.

- If OSA is not found, no further management is required by the sleep physician. A letter is written to communicate negative findings to the referring clinician.
- If OSA is found, a letter is written to communicate findings and proposed management by the sleep physician to the referring clinician. Depending on the findings, management options include onward referral for adenotonsillectomy, conservative treatment and monitoring, or initiation of CPAP/NIV.
- If the test fails through insufficient data or is inconclusive, a repeat Level 1 study is likely to deliver a successful result.

Describe and explain any differences in the healthcare resources used *after* the proposed health technology vs. the comparator health technology:
There are no differences in healthcare resources utilised after the proposed health technology compared to the comparator health technology apart from the cost differential if a repeat study is required, when a repeat Level 2 study will cost less compared to a repeat Level 1 study. Failure rates for Level 1 studies are less than 5% and around 5% for Level 2 studies.

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

See Appendix A

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)?

☐ Superior
☒ Non-inferior
☐ 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 (see inclusion and exclusion criteria above) 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.

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?
The proposed technology seeks to expedite wait times and improve access for those children who are suitable for a home test, allowing the prioritisation of medically complex patients for Level 1 studies. Current wait times across Australia exceed the recommended timeframes within which treatment for OSA for children is required. A proportion of children and their families would also prefer to have their study undertaken in the child's usual (home) sleep environment.

Identify how the proposed technology achieves the intended patient outcomes:
The proposed technology facilitates reduction in wait times and timely delivery of treatment by providing an alternative diagnostic study for children suspected with OSA who are not medically complex as detailed previously.

For some people, compared with the comparator(s), does the test information result in:

A change in clinical management?	Yes
A change in health outcome?	Yes
Other benefits?	Yes

Please provide a rationale, and information on other benefits if relevant:
The change in clinical management is expedited diagnostic testing for non-medically complex children suspected of having OSA (see criteria under "population"). This will result in earlier treatment decisions and earlier delivery of definitive treatment of OSA. In addition to earlier symptomatic improvement and resolution of the OSA the other longer-term benefits that are expected include reduced consequences of untreated OSA (e.g. cardiovascular, cognitive and behavioural, metabolic) and decreased health care utilisation which is high with untreated OSA.[1-6] Other benefits include capacity to prioritise the comparator Level 1 study for medically complex children ensuring these children can also receive timely diagnosis and treatment.

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?

☐ More costly
☐ Same cost
☒ Less costly

Provide a brief rationale for the claim:

The proposed technology reduces the cost by avoiding the need for continuous overnight monitoring by a sleep technician as is required for the comparator (Level 1 study). Without this continuous monitoring, there may be a small reduction in data quality as a technician is not continuously monitoring signals being received from the equipment. However, with current Level 2 study equipment available, the failure rate is still quite low in patients in the proposed age range (at least 3yrs of age but less than 18yrs of age) at around 5%, which is similar to the failure rate to the comparator Level 1 PSG.

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',

	Type of study design*	**Title of journal article or research project** (including any trial identifier or study lead if relevant)	**Short description of research** (max 50 words)**	**Website link to journal article or research** (if available)	**Date of publication*****
1.	Comparative study of diagnostic accuracy	Withers, A, Maul, J, Rosenheim, E, O'Donnell, A, Wilson, A, and Stick, S (2022). Comparison of home ambulatory type 2 polysomnography with a portable monitoring device and in-laboratory type 1 polysomnography for the diagnosis of obstructive sleep apnea in children. Journal of Clinical Sleep Medicine, 18(2): 393-402,	L2PSG in the home is feasible with excellent concordance with L1PSG for the purposes of diagnosing OSA in children aged 5–18 years. Comparison of home L2PSG to L1PSG for diagnosing OSA showed a false-positive rate of 6.6% and false-negative rate of 3% for those performed at home.	https://doi.org/10.5664/jcsm.9576	2022
2.	Comparative study of diagnostic accuracy	Cielo CM, Kelly A, Xanthopoulos M, Pipan M, Arputhan A, Walega R, et al. Feasibility and performance of home sleep apnea testing in youth with Down syndrome. J Clin Sleep Med. Apr 27 2023	Youth 6 to 25 years old with Down syndrome were recruited to undergo both L1PSG and L2PSG. Compared to L1PSG, sensitivity of L2PSG was: 0.81, specificity was 0.75, accuracy was 0.8 including 2 youth whose L2PSG demonstrated OSA when L1PSG did not.	https://doi.org/10.5664/jcsm.10610	2023
3.	Single arm study of diagnostic accuracy	Goodwin JL, Enright PL, Kaemingk KL, Rosen GM, Morgan WJ, Fregosi RF, et al. Feasibility of using unattended polysomnography in children for research-report of the Tucson Children's Assessment of Sleep Apnea study (TuCASA). Sleep. 2001;24(8):937-44.	157 children aged 5-12 years underwent L2 PSG for investigation of sleep disordered breathing. Failure rate was 9% which reduced to 3% when a successful second unattended study was completed.	https://doi.org/10.1093/sleep/24.8.937	2001

	Type of study design*	**Title of journal article or research project** (including any trial identifier or study lead if relevant)	**Short description of research** (max 50 words)**	**Website link to journal article or research** (if available)	**Date of publication*****
4.	Single arm study of diagnostic accuracy	Goodwin JL, Kaemingk KL, Fregosi RF, Rosen GM, Morgan WJ, Sherrill DL, et al. Clinical outcomes associated with sleep-disordered breathing in Caucasian and Hispanic children - The Tucson Children's Assessment of Sleep Apnea Study (TuCASA). Sleep. 2003;26(5):587-91.	L2PSG were completed on 239 children aged 6-11 years for investigation of OSA. Values of RDI corresponded to clinical symptoms in children ages 6 to 11 years.	https://doi.org/10.1093/SLEEP%2F26.5.587	2003
5.	Single arm study of diagnostic accuracy	Goodwin JL, Kaemingk KL, Mulvaney SA, Morgan WJ, Quan SF. Clinical screening of school children for polysomnography to detect sleep-disordered breathing--the Tucson Children's Assessment of Sleep Apnea study (TuCASA). Journal of clinical sleep medicine 2005;1(3):247-54.	Describes the associations, specificities, sensitivities, and positive likelihood ratios of clinical symptoms to a finding of OSA in children 6-11 years. 480 L2PSGs. No comparison with L1PSG. Snoring, excessive daytime sleepiness, and learning problems are each specific, but not sensitive, for OSA.	https://doi.org/10.5664/jcsm.26338	2005
6.	Single arm study of diagnostic accuracy	Griffiths A, Mukushi A, Adams AM. Telehealth-supported level 2 pediatric home polysomnography. Journal of Clinical Sleep Medicine. 2022;18(7):1815-21.	A retrospective audit was conducted from 2013 to 2020. 239 L2PSG reports in children aged 5–18 years referred for suspected OSA. Telehealth-supported pediatric L2PSG achieved technical success in almost 90% of patients, with 89.5% achieving ≥ 6 hours sleep duration and excellent family acceptability.	https://doi.org/10.5664/jcsm.9982	2022
7.	Single arm study of diagnostic accuracy	Ioan I, Weick D, Schweitzer C, Guyon A, Coutier L, Franco P. Feasibility of parent-attended ambulatory polysomnography in children with suspected obstructive sleep apnea. Journal of Clinical Sleep Medicine. 2020;16(7):1013-9.	57 children aged 3-16 years were prospectively included in the trial of L2PSG. L2PSG was technically acceptable in 46 (81%). Failure due to nasal cannula was observed in 11% (n = 6), oximetry in 7% (n = 4), and both in 2% (n = 1) of cases.	https://doi.org/10.5664/jcsm.8372	2020

	Type of study design*	**Title of journal article or research project** (including any trial identifier or study lead if relevant)	**Short description of research** (max 50 words)**	**Website link to journal article or research** (if available)	**Date of publication*****
8.	Single arm study of diagnostic accuracy	Marcus CL, Traylor J, Biggs SN, Roberts RS, Nixon GM, Narang I, et al. Feasibility of comprehensive, unattended ambulatory polysomnography in school-aged children. Journal of Clinical Sleep Medicine. 2014;10(8):913-8.	201 children, born premature with birth weights of 500-1,250 grams, currently aged 5-12 years and living in Canada and Australia, underwent L2PSG.. L2PSG was technically satisfactory in 183 (91%). Fourteen studies were satisfactory when repeated, resulting in an overall rate of 197 (98%) satisfactory studies.	https://doi.org/10.5664/jcsm.3970	2014
9.	Single arm study of diagnostic accuracy	Russo K, Greenhill J, Burgess S. Home (Level 2) polysomnography is feasible in children with suspected sleep disorders. Sleep Medicine. 2021;88:157-61.	Fifty-five patients, aged 4 months to 18 years, underwent L2PSG. Technical success on the first attempt, was achieved for 48/55 (87%) subjects. 12% of caregivers found studies at home difficult and 8% preferred a hospital L1PSG.	https://doi.org/10.1016/j.sleep.2021.10.024	2021

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes. For yet to be published research, provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

**** If the publication is a follow-up to an initial publication, please advise. For yet to be published research, include the date of when results will be made available (to the best of your knowledge).*

Identify yet-to-be-published research that may have results available in the near future (that could be relevant to your application).

	Type of study design*	**Title of journal article or research project** (including any trial identifier or study lead if relevant)	**Short description of research** (max 50 words)**	**Website link to journal article or research** (if available)	**Date of publication*****
1.	**N/A**				

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes. For yet to be published research, provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

**** If the publication is a follow-up to an initial publication, please advise. For yet to be published research, include the date of when results will be made available (to the best of your knowledge).*

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1. Gozal, D., *Obstructive sleep apnea in children: implications for the developing central nervous system.* Seminars in pediatric neurology, 2008. **15**(2): p. 100-106.
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3. Tran, K.D., et al., *Child behavior and quality of life in pediatric obstructive sleep apnea.* Arch Otolaryngol Head Neck Surg, 2005. **131**(1): p. 52-7.
4. Mitchell, R.B., *Adenotonsillectomy for obstructive sleep apnea in children: outcome evaluated by pre- and postoperative polysomnography.* Laryngoscope, 2007. **117**(10): p. 1844-54.
5. Mitchell, R.B. and J. Kelly, *Outcome of adenotonsillectomy for obstructive sleep apnea in obese and normal-weight children.* Otolaryngol Head Neck Surg, 2007. **137**(1): p. 43-8.
6. Friedman, M., et al., *Updated systematic review of tonsillectomy and adenoidectomy for treatment of pediatric obstructive sleep apnea/hypopnea syndrome.* Otolaryngol Head Neck Surg, 2009. **140**(6): p. 800-8.

Appendix A - Proposed management of suspected OSA paediatric cases by sleep specialists