Summary of PICO/PPICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC). Four PICO sets are defined for out-of-laboratory sleep studies in children and adolescents with sleep disordered breathing (SDB):

- Set 1 – Level 2 polysomnography (PSG) study for diagnosis of obstructive sleep apnoea (OSA)
- Set 2 – Level 3 cardiorespiratory study for diagnosis of OSA in patients who are unable to tolerate a PSG
- Set 3 – Level 3 cardiorespiratory study for treatment monitoring of OSA
- Set 4 – Level 4 pulse oximetry study for diagnosis of OSA in patients who are unable to access an accredited paediatric sleep laboratory (i.e. reside in Modified Monash model areas MM2-MM7).

Note: This PICO confirmation was considered at the August 2022 and December 2022 PICO Advisory Sub-Committee (PASC) meeting. Following the December 2022 PASC meeting, in light of the outstanding issues highlighted by PASC for the Level 4 pulse oximetry study, the applicant has decided to not progress PICO set 4 (Level 4 pulse oximetry studies) as part of this application. The applicant intends to submit a separate application for Level 4 pulse oximetry studies at a later date after resolving the issues raised by PASC. For completeness, the PICO and PASC discussion of the issues that pertain to Level 4 pulse oximetry studies are included in Appendix G in this document. December 2022 PASC advice is shown using italic text.

Table 1 PICO for out-of-laboratory sleep (Level 2 PSG) studies in children and adolescents: PICO Set 1

Component	Description	
Population	Children aged 3 to <12[a] and adolescents aged 12 to <18[b] years with sleep disordered breathing (SDB) that have been: i. referred by a medical practitioner to a qualified paediatric or adult[b] sleep medicine practitioner who has determined that the patient has a high probability of symptomatic, moderate to severe obstructive sleep apnoea (OSA), and ii. following professional attendance of the patient (either face-to-face or by video conference) by a qualified paediatric or adult[b] sleep medicine practitioner who determines that investigation is necessary to confirm the diagnosis of OSA and that an out-of-laboratory setting is appropriate for the sleep study.	
Intervention	Level 2 polysomnography (PSG) study in an out-of-sleep-laboratory setting with a minimum of 7 channels including EEG, EOG, EMG, ECG, airflow, respiratory effort and oxygen saturation. After clinical assessment, addition of transcutaneous carbon dioxide monitoring may be considered.	
Comparator/s	Level 1 PSG studies under MBS #12210 & #12213	
Reference standard	Level 1 PSG study in an accredited sleep laboratory with 12-13 recording channels routinely recorded, and trained sleep laboratory staff in attendance.	
Outcomes	Testing success	Failed test Repeat testing Referrals for Level 1 PSG studies
	Technical performance	Sensitivity Specificity Positive and negative predictive values Rates of false positive and false negative results
	Change in management	Referral for ENT or craniofacial surgery Time from primary care referral to diagnosis [Level 1 PSG study referral outcome above]
	Patient outcomes	Improvement in neurocognitive performance, and cardiorespiratory illness Sleep outcomes (measure of interrupted sleep or sleep improvement; sleep-related behavioural problems; reduction in surrogate measures e.g., obstructive AHI, desaturations) Quality of Life
	Safety	Device issues: Skin reactions and lead entanglement Nosocomial infections avoided

Component	Description	
	Health system outcomes	Health care utilisation Wait-list times
Assessment questions	What is the safety, effectiveness and cost-effectiveness of a Level 2 PSG versus a Level 1 PSG study in children aged 3 to <12 and adolescents aged 12 to <18 years with a high probability for symptomatic, moderate to severe OSA?	

Abbreviations: AHI=apnoea / hypopnoea index; CPAP=continuous positive airway pressure; ECG=electrocardiogram; EEG=electroencephalogram; EMG=electromyogram; ENT=ear, nose and throat; EOG=electrooculogram; MBS=Medicare Benefits Schedule; OSA=obstructive sleep apnoea; SDB=sleep disordered breathing; PSG=polysomnography.

[a] Item 1 of proposed new MBS item numbers is for children.

[b] Item 2 of proposed new MBS item numbers is for adolescents; adolescents may be referred to paediatric or adult sleep medicine practitioners.

Table 2 PICO for out-of-laboratory sleep (Level 3 cardiorespiratory) study for diagnosis of OSA in children and adolescents: PICO Set 2

Component	Description	
Population	Children aged 3 to <12[a] and adolescents aged 12 to <18[b] years with sleep disordered breathing (SDB): i. who have been referred by a medical practitioner to a qualified paediatric or adult[b] sleep medicine practitioner who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea (OSA), and ii. following professional attendance of the patient (either face-to-face or by video conference) by a qualified paediatric or adult[b] sleep medicine specialist who determines that investigation is necessary for the diagnosis of OSA, and iii. patients who are or likely to be intolerant of head leads when full polysomnography (PSG) attempted. This may include patients with severe behavioural issues, sensory intolerance and/or Autism Spectrum Disorder.	
Intervention	Level 3 cardiorespiratory study in out-of-sleep-laboratory setting with a minimum of 4 channels including ECG or heart rate, airflow, respiratory effort and oxygen saturation. EEG, EOG and EMG are not included. After clinical assessment, addition of transcutaneous carbon dioxide monitoring may be considered.	
Comparator/s	Main: No sleep study and standard non-CPAP management	
Reference standard	Level 1 PSG study in an accredited sleep laboratory with 12-13 recording channels routinely recorded, and trained sleep laboratory staff in attendance.	
Outcomes	Testing success	Failed test Repeat testing Referrals for Level 1 PSG studies Referrals for Level 2 PSG studies
	Technical performance	Sensitivity Specificity Positive and negative predictive values Rates of false positive and false negative results
	Change in management	Time from primary care referral to diagnosis [Level 1 and 2 PSG study referral outcomes above]
	Patient outcomes	Improvement in neurocognitive performance, and cardiorespiratory illness Sleep outcomes (measure of interrupted sleep or sleep improvement; sleep-related behavioural problems; reduction in surrogate measures e.g., obstructive AHI, desaturations) Quality of Life
	Safety	Device issues: Skin reactions and lead entanglement Nosocomial infections avoided
	Health system outcomes	Health care utilisation Wait-list times
Assessment questions	What is the safety, effectiveness and cost-effectiveness of a Level 3 cardiorespiratory study versus no sleep study and standard non-CPAP management in children aged 3 to <12 and adolescents aged 12 to <18 years at risk for significant OSA and intolerant or likely to be intolerant of head leads for PSG setup?	

Abbreviations: AHI=apnoea / hypopnoea index; BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ECG=electrocardiogram; EEG=electroencephalogram; EMG=electromyogram; ENT=ear, nose and throat; EOG=electrooculogram; MBS=Medicare Benefits Schedule; OSA=obstructive sleep apnoea; SDB=sleep disordered breathing; PSG=polysomnography.

[a] Item 1 of proposed new MBS item numbers is for children.

[b] Item 2 of proposed new MBS item numbers is for adolescents; adolescents may be referred to paediatric or adult sleep medicine practitioners.

Table 3 PICO for out-of-laboratory sleep (Level 3 cardiorespiratory) study for treatment monitoring in children and adolescents: PICO Set 3

Component	Description	
Population	Children aged 3 to <12[a] and adolescents aged 12 to <18[b] years with sleep disordered breathing (SDB) that have been: i. referred by a medical practitioner to a qualified paediatric or adult[b] sleep medicine practitioner who has determined that the patient is stable on current respiratory support for SDB, and ii. following professional attendance of the patient (either face-to-face or by video conference) by a qualified paediatric or adult[b] sleep medicine specialist who determines that investigation is necessary to assess respiratory support therapy [continuous positive airway pressure- CPAP or bilevel positive airway pressure- BiPAP].	
Intervention	Level 3 cardiorespiratory study in out-of-sleep-laboratory setting with a minimum of 4 channels including ECG or heart rate, airflow, respiratory effort and oxygen saturation. EEG, EOG and EMG are not included. After clinical assessment, addition of transcutaneous carbon dioxide monitoring may be considered.	
Comparator/s	Main: Level 1 PSG studies every 6 months under MBS #12210, #12213, #12215 and #11217	
Reference standard	Level 1 PSG study in an accredited sleep laboratory with 12-13 recording channels routinely recorded, and trained sleep laboratory staff in attendance.	
Outcomes	Testing success	Failed test Repeat testing
	Technical performance	Sensitivity Specificity Positive and negative predictive values Rates of false positive and false negative results
	Change in management	Adjustment or change to CPAP / BiPAP breathing support Monitoring / review frequency
	Patient outcomes	Improvement in neurocognitive performance, and cardiorespiratory illness Sleep outcomes (measure of interrupted sleep or sleep improvement; sleep-related behavioural problems; reduction in surrogate measures e.g., obstructive AHI, desaturations) Quality of Life
	Safety	Device issues: Skin reactions and lead entanglement Nosocomial infections avoided
	Health system outcomes	Health care utilisation Wait-list times
Assessment questions	What is the safety, effectiveness and cost-effectiveness of a Level 3 cardiorespiratory study for treatment monitoring versus monitoring with a Level 1 PSG study every 6 months in children aged 3 to <12 and adolescents aged 12 to <18 years who are stable on CPAP or BiPAP respiratory support?	

Abbreviations: AHI=apnoea / hypopnoea index; BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ECG=electrocardiogram; EEG=electroencephalogram; EMG=electromyogram; ENT=ear, nose and throat; EOG=electrooculogram; MBS=Medicare Benefits Schedule; OSA=obstructive sleep apnoea; SDB=sleep disordered breathing; PSG=polysomnography.

[a] Item 1 of proposed new MBS item numbers is for children.

[b] Item 2 of proposed new MBS item numbers is for adolescents; adolescents may be referred to paediatric or adult sleep medicine practitioners.

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of out-of-laboratory sleep studies (Levels 2, 3 and 4) for the investigation of sleep disordered breathing (SDB) in children and adolescents (age 3 to <18 years for Levels 2 PSG and Level 3 cardiorespiratory studies and 1 to <18 years for Level 4 pulse oximetry studies) was received from Australasian Sleep Association (ASA) by the Department of Health and Aged Care. Note: following the December 2022 PASC meeting, the applicant has decided to not progress with seeking MBS listing for Level 4 pulse oximetry studies at this time. The PICO and PASC discussion of the issues that pertain to Level 4 pulse oximetry studies are included in Appendix G in this

document and the applicant intends to submit a separate application for Level 4 pulse oximetry studies at a later date after resolving the issues pertaining to Level 4 pulse oximetry studies.

The applicant's clinical claim is that:

- Level 2 PSG study is non-inferior to Level 1 PSG in children aged 3 to <12 and adolescents aged 12 to <18 years at risk for significant OSA (PICO set 1).
- Level 3 cardiorespiratory study (diagnostic) is superior to no sleep study and standard non-CPAP management in children aged 3 to <12 and adolescents aged 12 to <18 years at risk for significant OSA and intolerant or likely to be intolerant of head leads for full PSG setup (PICO set 2).
- Level 3 cardiorespiratory study (monitoring) is non-inferior to Level 1 PSG in children aged 3 to <12 and adolescents aged 12 to <18 years who are stable on CPAP or BiPAP respiratory support (PICO set 3).

The application discussed key limitations to gaining access to a Level 1 PSG study within an accredited sleep laboratory:

- Most accredited paediatric sleep laboratories have > 12 month waiting lists to access sleep studies.
- Limited capacity for the number of diagnostic PSGs within sleep laboratories.
- All accredited paediatric sleep laboratories are located mostly in the capital cities.
- The COVID-19 pandemic has had significant impact on waiting lists, particularly in Sydney and Melbourne.

The application claimed (p43) that the benefits of the proposed service were improved access to sleep monitoring services, improved consumer satisfaction, reduced wait times for Level 1 PSG studies, reduced time to diagnosis and treatment of SDB with reduction in health care utilisation.

Current MBS items for sleep studies are summarised in Table 4.

Table 4 Existing MBS items for sleep studies in children, adolescents and adults

MBS#	Age	Sleep Study Type	Fee	Purpose	Maximum Frequency
MBS items for sleep studies in children/adolescents					
12210	3 to <12 yr	Level 1	$742.00	Investigation / diagnosis of suspected OSA in children	3 per 12 mo
12213	12 to <18 yr	Level 1	$668.45	Investigation / diagnosis of suspected OSA in adolescents	3 per 12 mo
12215	3 to <12 yr	Level 1	$742.00	Further investigation in a child who had 3 studies under #12210	1 per 12 mo
12217	12 to <18 yr	Level 1	$668.45	Further investigation in an adolescent who had 3 studies under #12213	1 per 12 mo
MBS items for sleep studies in adults					
12203	≥ 18 yr	Level 1	$621.60	Investigation / diagnosis of suspected OSA in adults	1 per 12 mo
12204	≥ 18 yr	Level 1	$621.60	Initiation of CPAP treatment in an adult with diagnosed SDB	1 per 12 mo
12205	≥ 18 yr	Level 1	$621.60	Follow-up (monitoring) in an adult with diagnosed SDB	1 per 12 mo
12207	≥ 18 yr	Level 1	$621.60	Further investigation in an SDB adult who has failed CPAP	1 per 12 mo
12208	≥ 18 yr	Level 1	$621.60	Repeat study in an adult who failed to sleep under #12203	1 per 12 mo
12250	≥ 18 yr	Level 2	$354.45	Investigation / diagnosis of suspected OSA in adults	1 per 12 mo

Source: Medicare Benefits Schedule (1 November 2022).
Abbreviations: CPAP=continuous positive airway pressure; MBS=Medicare Benefits Schedule; OSA=obstructive sleep apnoea; PSG=polysomnography; SDB=sleep disordered breathing.

The MBS cites explanatory notes for these items "DN.1.17 Investigations for sleep disorders [Items 12203 to 12250]" with information including specified screening questionnaires, and relative contraindications, billing rules and other information.

The aim of introducing out-of-laboratory testing is to:

- reduce time from referral to diagnosis and definitive treatment for suspected OSA, and thus improve the likelihood the child will avoid long-term sequelae from untreated OSA
- improve access to sleep studies thus reducing unnecessary ear, nose and throat (ENT) surgeries and also to ensure ENT surgery in higher risk patients is conducted in the correct setting
- expand treatment available to children and adolescents currently denied access in rural and remote areas.

MBS funding for out-of-laboratory studies would also relieve the burden on present paediatric sleep laboratories. The applicant indicated that the intention was to increase throughput by assessing less complicated patients with Level 2 PSG studies so that Level 1 PSG studies could be focused towards complex patients and facilitate respiratory support (initiation of continuous positive airway pressure [CPAP] or bilevel positive airway pressure [BiPAP], dose titration and tolerance check).

A draft PICO Confirmation for this application was considered at the August 2022 meeting of PASC.

At the August 2022 PASC meeting, PASC noted that MSAC has previously considered unattended sleep studies in the diagnosis of OSA in 2010 (MSAC application 1130). PASC noted that MSAC supported public funding of Level 2 PSG studies for adults but not children. MSAC did not support public funding of Level 3 cardiorespiratory or Level 4 pulse oximetry studies for adults or children. PASC (August 2022) also noted a number of issues required resolution before ratification of the PICO, including:

- Address the issues with the clinical algorithms and further revise accordingly.
- Clarify and confirm the population definitions and eligibility criteria.
- Address the issues raised regarding the proposed interventions, including but not limited to performance, limitations and management of patients following each sleep study.
- Seek input from clinical experts, including ENT surgeons to help inform the clinical algorithms.
- Provide separate PICO sets for diagnosis and treatment monitoring for Level 3 cardiorespiratory sleep studies.
- Revise the outcomes for each PICO set once the clinical algorithms are revised.
- Create separate item descriptors for diagnosis and treatment monitoring in paediatric and adolescent populations for Level 3 cardiorespiratory study.
- Address MBS item descriptor issues.
- Resolve the fee discrepancy issue and provide justifications for the proposed fee.

At the August 2022 PASC meeting, PASC noted that the applicant's clinical experts may be able to provide advice to resolve some of the issues. However, PASC (August 2022) advised that given the number of issues to be resolved, and the need for consultation to confirm the treatment algorithm, an updated PICO would need to be reconsidered at the December 2022 PASC meeting.

The main differences between the updated PICO prepared for the December 2022 PASC meeting and the PICO considered at the August 2022 PASC meeting are summarised in Table 5.

Table 5 Issues raised by PASC at August 2022 meeting

Issue	Comment	Addressed In
Clinical algorithms	Algorithms refined based on applicant feedback and revised populations / eligibility criteria. Additional algorithm included to capture flow of patients to ENT surgery from primary care.	See Clinical management algorithms
Populations Eligibility criteria	Populations / eligibility criteria revised based on applicant feedback. Tabulated summary information included where possible throughout the document for clarity.	See summary Table 6
Issues including performance, limitations and management of patients following each sleep study	Summary of performance characteristics presented where available. Changes in management for each study type now specified.	Summarised in Table 11 Summarised in Table 14
Input from clinical experts, including ENT surgeons	Reflected throughout this document	Reflected throughout this document
Separate PICO sets for diagnosis and treatment monitoring for Level 3 cardiorespiratory sleep studies	Changes made to PICO Sets and Population sections. Flow-on changes to Intervention, Comparator and Outcomes. Additional Item and Descriptor.	See PICO Set 2 and PICO Set 3. Discussed under Population – PICO Set 2 and Population – PICO Set 3
Revise the outcomes for each PICO set	Outcomes add – new outcomes in blue text Outcomes.	See Outcomes.
Separate item descriptors for diagnosis and treatment monitoring in paediatric and adolescent populations for Level 3 cardiorespiratory study	Changes made to PICO Sets and Population sections.	See PICO Set 2 and PICO Set 3. Summarised in Table 8 and Table 17. Discussed under Proposed items
Address MBS item descriptor issues	Per PASC (August 2022) request, items split according to age group and diagnostic / monitoring purpose. Rationale added regarding fees, maximum frequency.	Summarised in Table 8 and Table 17. See Proposed descriptor text
Revised the proposed fees and resolve the fee discrepancy issue	Rationale regarding fully manual vs computer-assisted scoring added based on applicant feedback. However, the fees were not revised as requested by PASC (August 2022).	See discussion in Proposed fees. Requested fees presented in Table 17.

Abbreviations: ENT= ear, nose and throat; MBS=Medicare Benefits Schedule: PICO=Population, Intervention, Comparator, Outcome; PASC=PICO Advisory Sub-Committee

PICO criteria

Population

SDB is a common childhood disorder, which encompasses a spectrum of disorders that range in severity from snoring, central apnoea, abnormalities of ventilation, to obstructive sleep apnoea (OSA). OSA is the most prevalent type of SDB in children. Predisposing conditions include enlarged adenoids and tonsils, obesity, reduced neuromotor tone and abnormalities of airway shape or size. This PICO Confirmation concerns the use of unattended sleep studies in the paediatric population for diagnosis, treatment and monitoring of OSA.

OSA is defined as the presence of periods of partial upper airway obstruction and/or intermittent complete upper airway obstruction, leading to abnormalities in ventilation and/or sleep disruption. OSA occurs across all childhood age groups but has a peak incidence between two and eight years of age. OSA affects 1-5% of children (Marcus et al 2012; Lumeng and Chervin 2008). The consequences of 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.

OSA is currently treated using a range of therapies, including:

- continuous positive airway pressure (CPAP)
- ear, nose and throat (ENT) surgery (primarily adenotonsillectomy)
- craniofacial surgery (referred from specialists e.g., paediatricians)
- oral (dental) appliances (in children 7 years and older, mainly in adolescents)
- intra-nasal steroid or anti-inflammatory sprays (e.g., fluticasone)(less likely in very young children)
- weight loss in patients with obesity.

Suitability of these treatments will depend on the patient's age. Commencement on an intra-nasal spray may be initiated by a referring physician as a component of assessment for OSA risk and need for referral. ENT surgery, mainly adenotonsillectomy, is presently the mainstay of initial treatment for paediatric OSA.

With listing of the proposed out-of-laboratory items, in-laboratory PSG (Level 1) sleep studies would be intended to focus on the following groups, representing the highest need patients:

- Children younger than 3 years old
- Children and adolescents with suspected OSA at risk of hypoventilation (including obesity hypoventilation).
- Children and adolescents with SDB who have complex co-morbidities such as cardiac disease.
- Children and adolescents being investigated for other sleep disorders such as narcolepsy, parasomnias, restless legs syndrome.

Table 6 summarises (1) the anticipated Level 1 PSG study populations (italics) and (2) the other populations that are the subject of this application.

Table 6 Summary of proposed paediatric populations by sleep study type (scenario after items listed)

Study Type	Target Paediatric Population
Diagnostic	
Level 1	*Children under 3 years, children/adolescents 3 to <18 years at risk of hypoventilation (including obesity hypoventilation), or those 3 to <18 years with complex co-morbidities (such as cardiac disease) or other potential sleep disorders such as narcolepsy, parasomnias, restless legs syndrome.*
Level 2	Children/adolescents 3 to <18 years not at risk of hypoventilation (including obesity hypoventilation), without complex co-morbidities (such as heart disease) or other potential sleep disorders such as narcolepsy, parasomnias, restless legs syndrome, and with parental support for a home sleep study.
Level 3	Children/adolescents 3 to <18 years with severe behavioural issues, sensory intolerance, Autism Spectrum Disorder, and / or unable to tolerate head leads, and with parental support for a home sleep study.
Monitoring	
Level 1	*Children/adolescents 1 to <18 years on NIV or CPAP therapy assessed as likely to require significant change in titration.*
Level 3	Children/adolescents 3 to <18 years diagnosed with OSA and currently stable on BiPAP or CPAP.

Abbreviations: BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ENT=ear, nose, and throat; NIV=non-invasive ventilation; OSA=obstructive sleep apnoea.

Contraindications for an out-of-laboratory sleep study are:

- a lack of access to a safe setting for the study and/or
- a guardian who is reluctant or unable to supervise the study
- acute upper/lower respiratory tract infection (also a contraindication for Level 1 PSG).

At the August 2022 meeting, PASC requested clarification on why patients aged <3 years are considered high risk (and therefore not suitable for Level 2 PSG and Level 3 cardiorespiratory studies) but are suitable for Level 4 pulse oximetry studies. Level 1 and Level 2 PSG studies involve a relatively large amount of equipment and associated leads (to a lesser extent also Level 3 cardiorespiratory studies), potentially including a head cap for electroencephalography (EEG), probes attached to various areas of the face, multiple leads and attachment points for electrocardiography (ECG), a belt to measure inspiration and so on. This can result in lead entanglement which necessitates additional supervision of studies in children under 3 years of age. There is also a paucity of evidence in children younger than 3 years for Level 2 and 3 sleep studies. .

Population – PICO Set 1

The proposed populations for Level 2 PSG studies correspond to those for the current MBS items for Level 1 PSG studies (Items 12210 and 12213; see Table 4). That is, children younger than 12 years and adolescents aged 12 to <18 years, respectively. The exception is that the item for children younger than 12 years will also have a minimum age restriction of 3 years, as the applicant advises children below 3 years should only be evaluated in an in-laboratory setting (discussed in previous section above) . The applicant also suggested that Level 2 PSG studies should target uncomplicated patients and that high risk patients would not be appropriate for a Level 2 PSG study.

In determining if an out-of-laboratory setting is appropriate for the sleep study, the sleep medicine practitioner will rule out high risk patients, defined as those at risk of hypoventilation (including obesity hypoventilation), or with complex co-morbidities (such as heart disease) or suspected of potential sleep disorders such as narcolepsy, parasomnias or restless legs syndrome.

The application estimated that the number of patients eligible for Level 2 PSG studies in the first year, could be 30% of the number of patients wait-listed for Level 1 PSG studies (see Table 7). These would be

additional services to data for paediatric sleep studies (i.e., utilisation for MBS items 12210 and 12213 would remain unchanged).

Level 2 PSG studies are not indicated in children aged <3 years (as described above) or in patients with clinical concern regarding medical instability and ability to gain relevant information without experienced staff present. The proposed Level 2 PSG study items are for investigation of possible OSA only and are not proposed for patients who require sleep studies indicated for sleep movement disorders, suspected nocturnal seizures, atypical parasomnias, hypersomnia and narcolepsy, or initiation of respiratory support, and who would only be appropriate for Level 1 PSG studies.

Population – PICO Set 2

Level 3 cardiorespiratory studies are being proposed for the investigation of possible OSA in those children and adolescents where Level 1 or 2 PSG studies would be distressing or challenging, and who are unlikely to tolerate head leads (for the electroencephalogram (EEG), electrooculogram (EOG) and electromyography (EMG)). Otherwise, the populations for proposed Level 3 cardiorespiratory studies are the same as those for Level 2 PSG (PICO Set 1); that is, children aged 3 to <12 years and adolescents aged 12 to <18 years.

As a proxy, the applicant proposes patients falling into this category would be those who have not tolerated other medical investigations, who are likely to be highly anxious or who have limited tolerance for sensory stimulation (having neurocognitive conditions such as Autism Spectrum Disorder; also Rett, Prader-Willi, or Down syndromes). The application estimated that 5% of 9,390 wait-listed children would likely find the Level 1 or 2 PSG studies distressing or challenging (see Table 7).

Population – PICO Set 3

The Australian Sleep Association guideline for paediatric sleep studies (Pamula et al., 2017) recommends that children and adolescents receiving non-invasive respiratory support (CPAP/BiPAP) require routine review sleep studies every 6-12 months to ensure that efficacy of treatment is maintained with growth and development and to evaluate if therapy is still required or can be withdrawn. This recommendation and approximate frequency is consistent with guidelines from a number of overseas jurisdictions. The application stated that resource constraints prevent children requiring respiratory support from being monitored every 6-12 months (Chawla et al., 2021). The applicant proposes that a monitoring item for Level 3 cardiorespiratory studies would correct this (one item each for the two paediatric age groups).

The ASA guideline suggests that (instead of Level 1 or 2 PSG) Level 3 cardiorespiratory studies may be used to determine the effectiveness of therapy in the early stages of non-invasive respiratory support, particularly for less complicated patients. Paediatric patients not suitable for monitoring with a Level 3 cardiorespiratory study would be: those medically unstable on present respiratory support; those likely to require changes to respiratory support settings during the study; or patients who have suboptimal adherence or response to therapy.

An estimated 50% of paediatric patients presently on non-invasive breathing support are estimated to be stable. The application estimated that 1,045 children in Australia were on some form of respiratory support (CPAP or BiPAP) in 2019 (estimates are summarised in Table 7).

Note that a Level 3 cardiorespiratory study is not appropriate for initial titration for a patient commencing respiratory support (CPAP or BiPAP should be commenced using a Level 1 PSG study only) – this should be reflected in any listing of items for Level 3 cardiorespiratory studies if recommended.

PASC queried whether, for the treatment monitoring population (PICO 3), Level 2 studies may be more appropriate than Level 3 studies. The applicant confirmed that full PSG (Level 1 study) is used for patients

while they are being initiated on treatment, but once the patient's respiratory status (while on treatment) is stable, Level 3 studies are adequate for monitoring purposes. PASC noted there is a lack of high-quality evidence to guide frequency of monitoring and it is based on expert opinion only.

Population – summary of utilisation estimates

Based on a review of sleep laboratory data from three tertiary paediatric sleep centres, the application has derived estimates of the proportions of patients receiving Level 1 PSG diagnostic studies that could instead be eligible for the out-of-laboratory studies proposed in this application, when OSA is suspected (Table 7).

The applicant assumes that since current wait-list times are 12 months or longer, the wait-list size is equivalent to 12 months' utilisation under the current MBS items (items 12210, 12213, 12215, 1227), or 9,390 sleep studies. The utilisation from 2018/2019 for items 12210 and 12213 (7,748 and 1,621, or 9369 in total) is used as a proxy for the wait-lists for children aged <12 years and adolescents 12 to <18 years, respectively.

Table 7 Summary of utilisation assumptions and estimates for proposed items

PICO Set	Age	Study Type	Level 1 PSG wait-list estimate	Assumption / Proportion (based on Applicant review of wait listed patients)	Estimated Number of Patients
Diagnostic					
PICO Set 1	3 to <12 yr	Level 2	7,748	30% of patients likely to be eligible / uncomplicated	2,324
PICO Set 1	12 to <18 yr	Level 2	1,621		486
PICO Set 2	3 to <12 yr	Level 3	7,748	5% of patients likely to find head leads distressing or challenging	387
PICO Set 2	12 to <18 yr	Level 3	1,621		81
Monitoring					
PICO Set 3	3 to <12 yr	Level 3	**(1,045)	*50% of patients on breathing support are stable	*864
PICO Set 3	12 to <18 yr	Level 3			*181

* The utilisation from 2018/2019 for items 12210 and 12213 (7,748 and 1,621, or 9369 in total) is used as a proxy for the wait-lists for children aged <12 years and adolescents 12 to <18 years, respectively.
**The basis of the estimate for Level 3 cardiorespiratory (monitoring) studies is the number of children and adolescents on non-invasive breathing support for OSA in 2019 (1,045), not based on wait-list projections. The split of utilisation from the Level 1 PSG study wait-list projections has been used to generate estimates for the two age groups.

Data presented in the application stated that 782, 702 and 403 children were on the wait list for sleep studies in Queensland Children's Hospital (QCH), Children's Hospital at Westmead (Westmead) and Royal Children's Hospital (RCH) Melbourne respectively in 2021. The application form indicated that approximately 16-24 patients per week are able to undergo a Level 1 PSG study at these centres accounting for approximately 832 to 1248 Level 1 PSG studies per annum. This suggests that most patients would be able to undergo testing within 6-12 months of being added to the waiting list (without additional patients joining the wait-list).

The applicant provided wait-list data from representative hospitals (QCH, Westmead and RCH) which indicated that approximately 20-49% of children waiting for Level 1 PSG studies were waiting for a review study. The previous draft PICO Confirmation commented that a larger proportion of children at Westmead were able to access review studies without being wait-listed, than at QCH. It is possible this is due to the type of cases that may be referred to Westmead, which often sees the most complex cases in the Sydney Children's Hospitals network.

In the applicant's pre-PASC response for the August 2022 meeting, the applicant estimated that Australian paediatric hospital sleep laboratories are conducting 70-80% of Level 1 PSG studies in high risk patients due to their need for a sleep study being prioritised above lower risk patients. Therefore lower risk patients could be waiting a long time to access sleep studies.

The application estimated that 20% of the 9,390 currently on the waiting list live in regional, rural or remote areas. This is consistent with MBS claims data for 2021-2022 indicating there were 6,586 claims for MBS items 12210 and 12213, of which 1,276 claims (19.4%) were for patients residing in a regional, rural or remote area (defined here as MM2 – MM7) (see Appendix A - Paediatric sleep study MBS claims data).

At the August 2022 PASC meeting, PASC noted that if only 30% of patients on the wait list for Level 1 PSG studies met the criteria to be triaged for a Level 2 PSG study, the impact in terms of reduced waitlists will be modest.

PASC noted the applicant's claim that access to out-of-laboratory sleep studies could potentially shorten waiting times and enhance rural patients' access to sleep studies, and noted that waiting times for a Level 1 test appear to be substantial.

PASC considered the population estimates and noted the applicant estimated that 30% of patients currently on the waiting list may be suitable for a Level 2 study (PICO 1), which would attenuate the impact on waiting list times and time to diagnosis.

PASC agreed that patients eligible for a Level 3 diagnostic study (PICO 2) would represent only a small proportion (5%) of patients on the waiting list. Decisions about which children would be appropriate for a Level 3 diagnostic study would need to be at the discretion of the referring specialist because it is not possible to define every medical condition that would be eligible.

Following the December 2022 PASC meeting, the applicant clarified that the number of patients estimated to be eligible for Level 2, 3 and 4 (see Appendix G) sleep studies are additive. For example, the total number of children (3-<12 years) who undergo an out-of-laboratory sleeps study instead of a Level 1 sleep study is estimated to be 4,261 (of the 7,748 patients estimated to be on the Level 1 PSG wait-list). The applicant also advised that, as PICO set 4 (Level 4 pulse oximetry studies) is not being progressed as part of this application, for the time being until a separate application for Level 4 pulse oximetry studies is submitted, the estimated utilisation will need to be revised accordingly (i.e. the number of patients estimated to utilise Level 4 pulse oximetry in Appendix G will need to be redistributed to either Level 2 or Level 3 utilisation estimates as appropriate). Updated utilisation estimates will be undertaken during the evaluation phase.

Prior tests

The MBS item for Level 2 PSG studies in adults refers to the use of questionnaires prior to the study to establish likelihood of suspected OSA in the patient (item 12250(a)(i)). These sleep study criteria facilitate GPs to be able to request out-of-laboratory sleep studies for adults; the same criteria are not specified when a sleep physician requests an adult sleep study. In this application, it is proposed that only sleep physicians can request sleep studies for children.

The applicant noted that questionnaires are not widely used in paediatric sleep practice in Australia (in comparison with other countries such as the United Kingdom). This is partly because paediatric sleep specialists in Australia are trained through the sleep specialty pathway while sleep studies in the UK are ordered by paediatricians who are generalists. For these physicians (not qualified sleep specialists), the British Thoracic Society Guideline (2022) have suggested the use of questionnaires to help determine the need for OSA diagnostic investigations.

Since paediatric practitioners in Australia do not commonly use sleep questionnaires, and the applicant is not seeking these sleep studies to be ordered by paediatricians or other practitioners, there is no need to include sleep questionnaires as a 'prior test' in the PICO Sets for the proposed items.

Intervention

Proposed Items

The intervention for the proposed investigative service is sleep studies in children and adolescents performed in an out-of-sleep-laboratory setting for:

- the investigation of SDB in a child or adolescent potentially leading to a diagnosis of OSA
- treatment monitoring in a child or adolescent with diagnosed OSA
- triage testing of children with suspected OSA to determine suitability for referral for to an ENT surgeon.

The following types of items are proposed:

- Level 2 PSG study (PICO Set 1) – diagnostic
- Level 3 cardiorespiratory study (PICO Set 2) – diagnostic
- Level 3 cardiorespiratory study (PICO Set 3) – monitoring

Age groups, proposed fees and other information for individual items is summarised in Table 8 (a version of this table also including proposed fees and maximum frequency is presented elsewhere in Table 17).

Table 8 Proposed MBS sleep study items (incorporating PASC [August 2022] feedback)

#	Age	Study Type	Purpose
Diagnostic			
1	3 ≤12 yr	Level 2	Investigation / diagnosis of suspected OSA in children
2	12 ≤18 yr	Level 2	Investigation / diagnosis of suspected OSA in adolescents
3	3 ≤12 yr	Level 3	Investigation / diagnosis of suspected OSA in children unlikely to tolerate head leads
4	12 ≤18 yr	Level 3	Investigation / diagnosis of suspected OSA in adolescents unlikely to tolerate head leads
Monitoring			
9	3 ≤12 yr	Level 3	Follow-up (monitoring) in a child with diagnosed OSA
10	12 ≤18 yr	Level 3	Follow-up (monitoring) in an adolescent with diagnosed OSA

Abbreviations: OSA=obstructive sleep apnoea; yr=year.

Based on August 2022 PASC advice on the type and number of items, the proposed items have been divided according to age group (children under 12 years; adolescents 12 years and older) and purpose (diagnostic versus monitoring), with the applicant's proposed maximum permitted frequency included.

Types of sleep studies under consideration

Four types of sleep studies are relevant to this application, summarised in Table 9.

Table 9 Types of sleep studies

Sleep study	Description
Level 1	• PSG performed in a sleep laboratory • Trained sleep laboratory staff in attendance • 12-13 recording channels routinely recorded • Currently listed on the MBS for adults, adolescents and children • 8 hours' duration
Level 2	• PSG performed out-of-laboratory, at patient's home or other location • Leads application and equipment set-up: EITHER lead application and instruction provided in clinic prior to patient returning home OR technician travels to patient's home for lead set-up and instruction • No in-person sleep laboratory staff present at patient's home • Trained sleep technician available throughout the study at the sleep laboratory via telephone or other means • Parent/guardian in attendance. • Minimum of 7 channels recorded, including EEG, EOG, chin EMG, ECG, airflow, respiratory effort, SpO2. • Currently listed on the MBS only for adults • 8 hours' duration
Level 3	• Limited channel cardiorespiratory study performed out-of-laboratory, at patient's home or similar • Leads application and equipment set-up: EITHER lead application and instruction provided in clinic prior to patient returning home OR technician travels to patient's home for lead set-up and instruction • No in-person sleep laboratory staff present at patient's home • Trained sleep technician available throughout the study at the sleep laboratory via telephone or other means • Parent/guardian in attendance • Minimum of 4 channels monitored, including ECG or heart rate*, airflow, respiratory effort and SpO2 • Not currently listed on the MBS • 8 hours' duration

Source : Adapted from Table 1 of report for MSAC 1130 application and Pamula et al., 2017.

Abbreviations: CPAP=continuous positive airway pressure; ECG=electrocardiogram; EEG=electroencephalogram; EOG=electrooculogram ; EMG=electromyography; ENT=ear, nose & throat; MBS=Medicare Benefits Schedule; MSAC=Medical Services Advisory Committee; PSG=polysomnography; SpO_2=peripheral oxygen saturation; $TcCO_2$=transcutaneous carbon dioxide.

* Existing item descriptors for Level 1 and Level 2 PSG specify ECG. Previously PASC advised that ECG should be included as one of the channels for Level 3 as well. Whether it is appropriate for Level 3 item descriptor include "ECG" or "ECG or heart rate" will be assessed during the assessment phase.

Level 1 and 2 PSG studies record parameters relating to sleep state, ventilation, cardiac function, respiratory effort, body movements and leg movements. Aside from the setting, Level 1 and 2 PSG studies are intended to offer the same test.

Level 3 cardiorespiratory are not 'PSG' studies, and are sometimes described as 'abbreviated testing' or 'limited channel studies'. The key difference between Level 2 PSG and Level 3 cardiorespiratory studies, is that Level 3 cardiorespiratory studies do not record EEG. This can affect sensitivity of this study type to detect OSA.

Level 2 PSG Study (PICO Set 1)

The application indicated Level 2 PSG studies comprise a full PSG comparable to a Level 1 PSG study. A Level 2 PSG study records seven or more channels for continuous monitoring of cortical sleep stages, oxygen saturation, muscle activity and breathing. Recordings in accordance with guidelines are made as follows:

i) airflow
ii) EMG

iii) ECG
iv) EEG (minimum of 4 leads or in selected investigations, a minimum of 6 leads)
v) EOG
vi) oxygen saturation
vii) respiratory effort (movement of rib cage and abdomen, whether separately or together).

Measurement of carbon dioxide (end-tidal or $TcCO_2$) will be considered on a case-by-case basis by the sleep medicine specialist.

The duration of the Level 2 PSG overnight investigation of sleep should be at least eight hours to confirm a diagnosis of OSA. A repeat study is required if less than six hours of sleep were recorded or the data was of inadequate quality and should be followed up with an in-laboratory study.

Polygraphic records are 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 one minute (. Records are stored for the interpretation and preparation of a report by the sleep medicine specialist based on reviewing the direct original recording of polygraphic data from the patient. If the study is not technically adequate and a full report cannot be generated, a sleep medicine specialist determines if the study should be repeated in a sleep laboratory (i.e., Level 1 PSG study).

The outcome of the study is expressed as a total number of apnoea events (pauses in breathing) and hypopnoea events (episodes of shallow breathing) per hour. This is known as the apnoea/hypopnoea index (AHI), which is used, along with other clinical features, to diagnose OSA and its severity in paediatric patients as follows:

- Mild OSA: obstructive AHI of 1 to less than 5 events per hour
- Moderate OSA: obstructive AHI of 5 to 10 events per hour
- Severe OSA: obstructive AHI of more than 10 events per hour.

Only patients with OSA diagnosed as moderate or severe would be eligible for a CPAP. Those with only mild OSA would be managed with non-CPAP treatment options.

The application also stated that a small proportion of patients (<5%) would need a Level 1 PSG study following the Level 2 PSG study due to test failure (Russo et al., 2021; Griffiths et al., 2021). For these patients, the Level 2 PSG studies would be an additional service.

Level 3 Cardiorespiratory Studies (PICO Set 2 and 3)

Level 3 cardiorespiratory studies records a minimum of four channels for continuous monitoring of heart rate, airflow, respiratory effort and oxygen saturation. Recordings in accordance with guidelines (Pamula et al., 2017) are made as follows:

i) airflow
ii) oxygen saturation
iii) respiratory effort
iv) ECG.

Measurement of $TcCO_2$ will be considered on a case by case basis by the sleep medicine specialist. Polygraphic recordings are analysed and outcomes reported in the same manner as for Level 2 PSG studies. Level 3 cardiorespiratory studies rely on total recording time as the denominator of total sleep time (whereas Level 1 and 2 PSG studies use the EEG trace to determine total sleep time) – this can lead to

an over-estimation of sleep time and an underestimation of SDB event frequency. Level 3 cardiorespiratory studies cannot identify arousals or sleep stages due to lack of EEG.

The ASA paediatric sleep studies guideline (Pamula et al., 2017) describes the published literature suggesting that Level 3 cardiorespiratory studies typically have a high positive predictive value (PPV) for the presence of OSA but a significant false negative rate (low negative predictive value [NPV]). That is, the study is effective to 'rule in' OSA but cannot 'rule out' OSA. Some reports, especially involving younger children, found poorer performance in studies where parents had set up the equipment (for example, Poels et al., 2003). The ASA guideline cites Jacob et al., (1995) as a source of values for PPV, NPV and other performance parameters of Level 3 cardiorespiratory studies (see Table 11). However, the values were confusing and a publication from the last 5-10 years would be more appropriate to support performance of this methodology, especially with improvements in communications, (for example) internet connection of equipment that allows remote monitoring and other technological changes.

At the August 2022 PASC meeting, PASC raised a suite of issues regarding the proposed Level 3 cardiorespiratory studies, which for brevity are reproduced in the Appendix B - PASC comments from August 2022 meeting.

PASC recalled questions were raised at the August 2022 PASC meeting regarding the suitability of Level 3 sleep studies for treatment monitoring. PASC noted that the applicant had cited evidence to support the claimed use of Level 3 studies for treatment monitoring.

Clinical specialists and treatment setting

The proposed items for children aged <12 years will only be ordered by a qualified paediatric sleep medicine specialists. For adolescents aged 12 to <18 years, it is proposed Level 2and 3 studies can be ordered by either adult or paediatric sleep medicine practitioners. The applicant confirmed that the studies for adolescents could be undertaken in a paediatric or adult sleep laboratory and the data scored by a trained paediatric or adult technician.

Although the sleep studies proposed will be undertaken out of the clinic (at home or similar), the studies will be managed by a technician located at the laboratory (in the same way the technician would be present during an overnight stay at the clinic). A sleep physician at the laboratory (which performed the sleep study) will interpret and report the sleep study. The applicant advises there are approximately 12 paediatric sleep laboratories in Australia whereas there are more than 70 adult laboratories.

For most patients, these items would involve in-person consultations with the sleep specialist, one for ordering of the study and a second for the results. Some patients may attend the clinic/hospital in person for the consultation. For some patients however, some or all of these could be telehealth consultations. It is assumed, however, the consultation with the sleep technician (set-up and instructions) is included in the study item itself in the same way it would be for in-laboratory studies – thus no additional telehealth items should be co-claimable for the conduct of the study itself.

Only NATA accredited paediatric sleep laboratories should be eligible as providers of these services (discussed further in Proposed items p.31).

Equipment

A list of medical device equipment currently used in Australia for sleep studies was presented in the previous draft and is given in the **Appendix C -** Equipment for out-of-laboratory sleep studies. The proposed services are performed using sleep monitoring devices that have been validated for use in paediatrics. At the August 2022 PASC meeting, PASC noted Level 2 PSG studies require a lot of consumables (single use and multi-use).

It is anticipated that other suitable devices are likely to become available with advances in technology. The application did not provide a comparison between the devices in terms of cost, clinical utility, test accuracy and safety. Additional equipment to meet increased need for out-of-laboratory sleep studies may be borne as an out-of-pocket expense by the patient if not covered by sleep laboratories.

The equipment for the study will need to be set up – including initiation of appropriate programs, attachment of leads, instructions on using the monitoring machines. Two options are possible:

- equipment will be set up and the patient instructed on its use by a technician at the sleep clinic before the patient returns home with it, or
- equipment will be delivered, set up by a technician visiting the patient's home and applied to the patient.

The parent/caregiver is given instructions on how to check that recording is occurring. They are also given a contact number or digital link to the sleep laboratory for overnight support (i.e., trouble shooting if required).

Claimed benefits

The claimed benefits of listing these sleep study items put forward by the applicant are summarised in Table 10.

Table 8 Claimed benefits of paediatric sleep study item listing

Study Type	Claimed Benefits
Level 2 PSG studies	• Improved access to / reduced wait times for PSG sleep studies. • Improved diagnosis, treatment and monitoring of OSA • Improved access to Level 1 PSG studies for children in high-risk groups, which would improve access for those children to time sensitive interventions
Level 3 cardio-respiratory studies	Diagnosis: • Reduced wait times for access to a sleep study • Access to sleep study for paediatric patients who would find a Level 1 PSG study distressing / challenging (otherwise likely to lead to a failed in-laboratory study or no study undertaken) Monitoring: • Increase monitoring for children on respiratory support at the appropriate intervals, which allows for timely evaluation of the effectiveness of current, or newly implemented therapies

Abbreviations:; OSA=obstructive sleep apnoea; PSG=polysomnography.

Out-of-laboratory sleep studies would allow children and parents to remain at home for the sleep studies. While not a clinical benefit per se, this may provide a more realistic environment to replicate any sleep problems. For Level 3 cardiorespiratory studies, fewer machines and leads to manage should make these studies simpler / more tolerable for children and parents. The need for a trained sleep technician for the Level 2 PSG and Level 3 cardiorespiratory studies limits the availability of those items to patients in remote locations or at a distance from the nearest paediatric sleep laboratory.

Summary of performance

A summary of assumed performance characteristics of interest to the PASC and based on applicant feedback is given in Table 11. Only limited information was available. The applicant was only able to provide combined estimates for the rates of studies that failed (poor or inadequate data) or were inconclusive (data provide no clear outcome to rule OSA in or out). As noted above, the NPV and PPV values for Level 3 cardiorespiratory studies cited in the ASA paediatric guideline were confusing (see table footnote) and potentially out of date.

Table 9 Summary of available sleep study performance characteristics

Study Type	False Positives	False Negatives	Rates of failed or inconclusive studies
Level 2	Negligible	Not available.	5% (these patients would be referred for a Level 1 PSG study)
Level 3	Negligible [a PPV ≥70%]	[a NPV >90 %]	10-15% b 1-2% for monitoring studies

Source: Table compiled for this PICO Confirmation.

Abbreviations: CPAP=continuous positive airway pressure; ENT=ear, nose & throat; MBS=Medicare Benefits Schedule; NPV=negative predictive value; PPV=positive predictive value.

NPV = the ratio of true negatives to negative test results; PPV= the ratio of true positives to positive test results

[a] PPV and NPV values for Level 3 in the application response based on Jacob et al., 1995. *These values were confusing since the NPV was expected to be lower and the PPV much higher both for a method of this type and as argued by the applicant.*

[b] the 1-2% value for failed or inconclusive studies (Level 3 monitoring) were supplied by the applicant.

The 1-2% value for failed or inconclusive studies (Level 3 monitoring) were supplied by the applicant. The applicant clarified that the 1-2% failure rate for Level 3 cardiorespiratory monitoring studies is based on Australian clinical experience.

The applicant notes that false positive results are not a characteristic of sleep studies of any level because they rely on detection of characteristic patterns that cannot easily be replicated in the absence of OSA. The exception is if the patient has a respiratory illness causing an upper airway obstruction (in which case the study should in any case be cancelled).

The risk of a false negative result is generally attributable to inadequate data, which would be categorised as a test failure in the clinical algorithms. Another potentially false negative might result from a child having supine OSA who only sleeps prone for the full duration in the study. A child who doesn't sleep a minimum six hours during the study would result in a failed test result due to inadequate data.

PASC recalled concerns were raised at the August 2022 PASC meeting about Level 3 diagnostic studies overestimating the prevalence/severity of OSA compared with Level 1 and 2 studies, which could lead to over-treatment. PASC noted the summary of technical performance in Table 12 indicated that false positive rates are low for all levels of sleep studies. However, PASC was concerned about the relatively high rates of failed or inconclusive studies for Level 3 (and Level 4) studies and the cost implications to the MBS due to the need for repeated or additional testing in a significant number of cases. PASC reiterated that the diagnostic performance and the impact of false positive, failed or inconclusive tests would need to be considered in the assessment.

Comparator(s)

A summary of comparators for the proposed out-of-laboratory study types is provided in Table 12. A summary of existing MBS sleep study items is provided in Table 4 above.

Table 10 Comparators for the proposed study types

Study Type	Comparators
Level 2 PSG studies	Level 1 PSG studies under MBS #12210 & #12213
Level 3 cardio-respiratory studies	Diagnosis: • No sleep study and standard non-CPAP management Monitoring: • Main: Level 1 PSG studies every 6 months under MBS #12210, #12213, #12215 and #11217

Abbreviations: CPAP=continuous positive airway pressure; MBS=Medicare Benefits Schedule; PSG=polysomnography.

Standard non-CPAP management is defined as:

- ENT surgery (primarily adenotonsillectomy)
- craniofacial surgery (referred from specialists e.g., paediatricians)
- oral (dental) appliances (in children 7 years and older, mainly in adolescents)
- intra-nasal steroid or anti-inflammatory sprays (e.g., fluticasone)(less likely in very young children)
- weight loss in patients with obesity.

The most appropriate option will vary according to the age of the patient and the cause of their SDB. Following advice from the applicant, watchful waiting has been removed as one of the treatment options in standard non-CPAP management. An option of 'watchful waiting' had been included in the previous draft, but the applicant noted that this represents 'no treatment' and there was no circumstance in which a patient with symptomatic SDB or diagnosed OSA should remain untreated. Accordingly 'watchful waiting' has been removed from the standard non-CPAP management options.

Given current wait times for studies funded under these items are long, an appropriate comparator for a proportion of patients may also be 'no testing plus standard non-CPAP management'. It is not known how many patients abandon the wait-list or go untreated.

PASC agreed with the two comparators for Level 2 studies (PICO 1), which are existing Level 1 paediatric sleep studies (primary comparator) along with no sleep study and standard non-CPAP management (secondary comparator), given the extended waiting time for Level 1 studies. After further consideration out of session, PASC advised that no sleep study and standard non-CPAP management is not an appropriate comparator for Level 2 sleep studies. PASC noted that while some patients may experience long wait times and/or may choose to not wait for a Level 1 sleep study, this delay and/or choice does not mean the patients are ineligible or definitively unable to undergo or access a Level 1 sleep study. PASC considered that the comparator for Level 2 studies should be Level 1 sleep study only and if further evidence on the implications and impact of delayed testing is available then this can be incorporated into the comparative assessment.

For Level 3 diagnostic sleep studies (PICO 2), PASC agreed that Level 1 paediatric sleep studies is an appropriate comparator, but that no sleep study and standard management may be a better comparator because of issues around access and tolerability, which are particularly relevant to this patient population. After further consideration out of session, PASC advised that Level 1 sleep studies should be removed as a comparator as the population for Level 3 diagnostic studies defines a subgroup of patients that are unable to undergo a Level 1 sleep study. PASC considered that the comparator for Level 3 diagnostic sleep studies should be no sleep study and standard non-CPAP management, as long as the comparative assessment uses Level 1 sleep study as the reference standard and takes into account any reduced diagnostic accuracy for Level 3 diagnostic sleep studies compared to Level 1 sleep studies.

PASC also agreed with the main and secondary comparators for Level 3 monitoring studies (PICO 3), noting that relatively few patients are currently having a review study within the first 12 months of therapy commencement, perhaps due to difficulties accessing Level 1 studies. After further consideration out of session, PASC advised that no monitoring (secondary comparator) is not an appropriate comparator for Level 3 monitoring studies. For the same reasons as discussed for Level 2 sleep studies, PASC considered that the comparator for Level 3 monitoring studies should be Level 1 sleep studies only and if further evidence on the implications and impact of delayed testing is available then this can be incorporated into the comparative assessment.

Reference standard (for investigative technologies only)

The reference standard is a Level 1 PSG study in a NATA accredited sleep laboratory, with 12-13 recording channels routinely recorded, with trained healthcare professionals in attendance throughout the night

(Pamula et al., 2017). This type of study is currently funded under MBS items numbers 12210, 12213, 12215 and 11217 for children and adolescents (see above Table 4).

PASC agreed that the appropriate reference standard for all four PICOs is a Level 1 sleep study.

Outcomes

A summary of proposed outcomes is in Table 13.

Table 11 Summary of proposed outcomes

Type	Outcomes
Testing success	Failed test Repeat testing Referrals for Level 1 PSG studies (relevant to all diagnostic items) Referral for Level 2 PSG studies (relevant to Level 3 cardiorespiratory)
Technical performance	Sensitivity Specificity Positive and negative predictive values Rates of false positive and false negative results
Change in management	Referral for ENT or craniofacial surgery Adjustment or change to CPAP / BiPAP breathing support (relevant to Level 3 monitoring) Time from primary care referral to diagnosis Monitoring/review frequency [Sleep study referral outcomes above]
Patient outcomes	Improvement in neurocognitive performance, and cardiorespiratory illness Sleep outcomes (measure of interrupted sleep or sleep improvement; sleep-related behavioural problems; reduction in surrogate measures e.g., obstructive AHI, desaturations) Quality of Life
Safety	Device issues: Skin reactions and lead entanglement Nosocomial infections avoided
Health system outcomes	Health care utilisation Wait-list times

Abbreviations: AHI=apnoea / hypopnoea index; BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ENT=ear, nose & throat.

Regarding nosocomial infections avoided – these are understood to be mainly respiratory viruses and other infections. It is unclear how the outcome for the number of infections avoided by out-of-laboratory sleep study would be measured although recent experience with COVID-19 may provide in-laboratory incidence or transmission data. Based on the evidence available, it is likely the evaluation to assess the clinical claim will use a linked evidence approach. In the application, the proposed outcomes mainly reflect broader consequences of any change in patient management on the health system i.e., reduced wait times, time to diagnosis and treatment, health care utilisation (and long-term health consequences of OSA). Test performance outcomes were identified as relevant outcomes and results for sensitivity and specificity of the proposed investigative tests would need to be compared to the reference standard i.e., in-laboratory PSG (Level 1 study). Test performance outcomes are needed to determine flow-on effects of the different tests on subsequent evidence linkages i.e., how the proposed test would change patient management and its likely impact on final patient health outcomes.

The applicant also claimed that prompt diagnosis and appropriate treatment of OSA is associated with improvement in patient health outcomes due to an association between undiagnosed and poorly managed OSA and conditions such as impaired neurocognitive development, sleep-related behavioural problems and cardiorespiratory illness.

At the August 2022 PASC meeting, PASC advised that the outcomes would need further consideration once the clinical management algorithms are finalised. PASC (August 2022) noted the outcomes were the same across the different PICO sets but considered outcomes should be different for diagnostic versus treatment monitoring. PASC (August 2022) considered outcomes such as time to commencement of treatment, alteration of treatment and survival may be out of scope for the diagnostic pathway and may depend on multiple factors other than sleep study results. For example, to model the survival outcome requires consideration of quality of life and length of life.

PASC (August 2022) also considered that clarification of the consequences of false positive and negative results was required, i.e., the health outcomes for these patients, given there is potential that patients may receive results that are discordant with the presence or absence of OSA. PASC (August 2022) considered this was important noting this was one of the reasons why MSAC did not support public funding of unattended sleep studies for children in 2010 (MSAC application 1130).

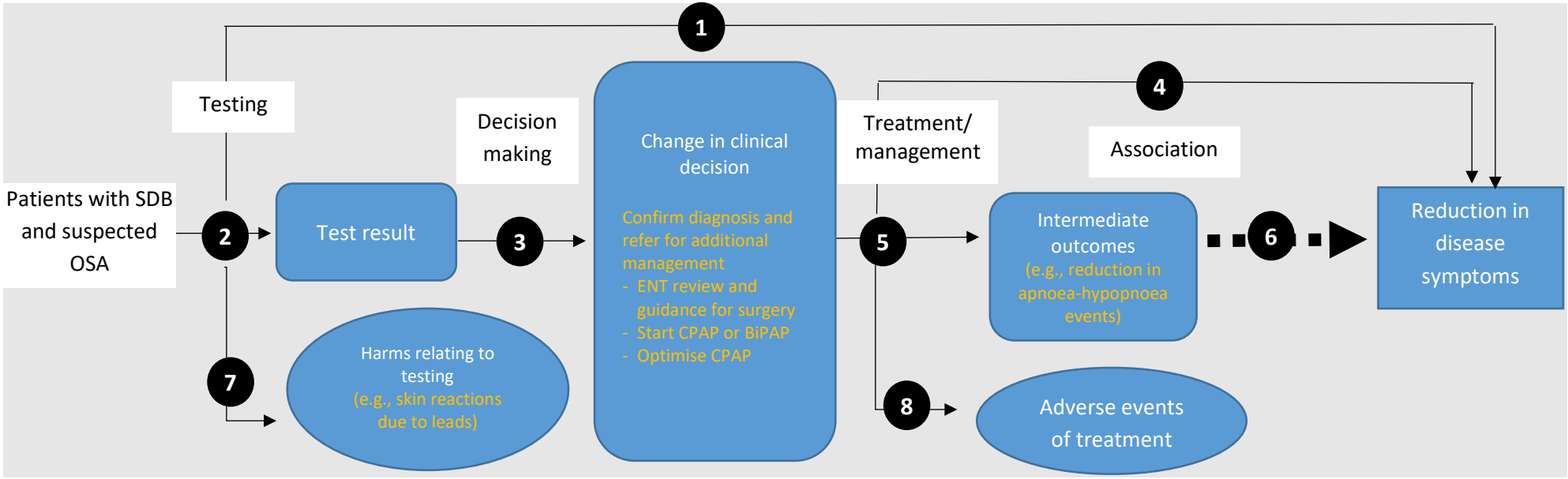
PASC (August 2022) discussed the inclusion of measuring impact on waitlist as an outcome. PASC (August 2022) considered this is complicated and needs to take into account a number of constraints including human resource factors, availability of equipment, impact of technical failures and inconclusive test, repeat studies and wait times. PASC (August 2022) noted the estimated current wait time is 6-12 months. PASC (August 2022) queried whether there is evidence on the impact of delayed diagnosis within this wait time for the patients who would be triaged for out-of-laboratory sleep studies (i.e., those who are not considered high risk). PASC (August 2022) noted that it would be beneficial for waiting lists for high risk and low risk patients to be listed as separate outcomes.

PASC noted that the outcomes had been refined since the previous PASC meeting in August 2022 and agreed that the broad set of outcomes defined for each PICO appear to be appropriate. PASC noted that test accuracy, changes in patient management and patient health outcomes are all important. PASC considered that outcomes such as health care utilisation and impact on waiting time will be complex to assess as these outcomes are driven by a range of factors including human resource factors, availability of equipment and the need for repeat studies due to technical failures and inconclusive test results.

Assessment framework (for investigative technologies)

It is likely the evaluation to assess the clinical claim would use a linked evidence approach. A suggested assessment framework is depicted in Figure 1. At the August 2022 PASC meeting, PASC did not discuss issues relating to the assessment framework and no changes have been made to this section following the August 2022 PASC consideration.

Figure 1 Assessment framework showing the links from the test population to health outcomes



Abbreviations: BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ENT=ear, nose and throat; OSA=obstructive sleep apnoea; SDB=sleep disordered breathing.

Figure notes: 1: direct from test to health outcomes evidence; 2: test accuracy; 3: change in diagnosis/treatment/management; 4: influence of the change in management on health outcomes; 5: influence of the change in management on intermediate outcomes; 6: association of intermediate outcomes with health outcomes; 7: adverse events due to testing; 8: adverse events due to treatment.

The application identified outcomes mostly related to health service utilisation and access that were not clinical effectiveness outcomes. Furthermore, the application did not provide evidence of the link between the proposed tests and what it called patient management outcomes (i.e., reduced wait times, time to diagnosis and treatment, health care utilisation) depicted by decision making (note 3 of Figure 1). Additional test accuracy outcomes (i.e., sensitivity and specificity) are needed to determine linkages to these patient management outcomes as per testing note 2 of Figure 1. Pending available evidence, alternatively, a direct evidence approach reporting impact of the proposed tests versus comparators on patient health outcomes such as reduction in disease symptoms (neurocognitive development, sleep-related behavioural problems, cardiorespiratory illness, survival and quality of life) may be considered. The available evidence may differ between the four proposed tests, warranting a consideration of what may be the most appropriate assessment framework for each.

In the previous MSAC consideration of unattended sleep studies for diagnosis in the paediatric setting, assessment by direct evidence and linked evidence approach was included (MSAC 1130 unattended sleep studies in the diagnosis of OSA, 2010). The direct evidence assessed the diagnostic effectiveness of unattended sleep studies with patient relevant outcomes (survival/mortality rate, reduction of symptoms and disease-specific quality of life); and surrogate outcomes (respiratory events/number of apnoeas or hypopnoeas, oxygen saturation, sleep time and efficiency and control of comorbidities).

As the direct evidence was limited and not of high quality, the linked evidence approach was also used to assess diagnostic accuracy of unattended sleep studies and their impact on patient management. The outcomes to assess diagnostic accuracy included sensitivity, specificity, accuracy, NPV and PPV. The outcomes to assess change in management following the use of the intervention included additional sleep studies (by type), referrals, time to diagnosis, time to commencement of treatment, alteration of treatment and treatment type.

PASC did not specifically discuss the Assessment Framework for PICO Sets 1-3. However, PASC acknowledged that there is new evidence that was not available in 2010 when MSAC previously considered the use of unattended sleep studies for diagnosis of OSA in the paediatric setting.

Clinical management algorithms

Clinical algorithms are presented as follows:

Current management of suspected OSA paediatric cases in primary care	Figure 2
Current management of suspected OSA paediatric cases by sleep specialists	Figure 3
Proposed management of suspected OSA paediatric cases by sleep specialists following listing of items	Figure 4
Current and proposed monitoring of diagnosed OSA cases stable on breathing support (CPAP or BiPAP)	Figure 5 & Figure 6

A summary of the various changes in clinical management depending on the sleep study outcomes, as understood by the evaluator, is in Table 14 for diagnosis and Table 15 for monitoring.

Table 12 Summary of changes in management – diagnosis of OSA

Study Type	Negative result	Positive result	Failed study	Inconclusive result
Level 2	AHI shows no OSA and data recording is adequate. Pursue further investigations for other causes of SDB.	AHI shows positive OSA diagnosis: Treat according to OSA severity and other clinical features (CPAP, or non-CPAP management)	Equipment failure or inadequate sleep – repeat study or refer for Level 1 PSG study.	Data available but cannot rule in nor rule out OSA – refer for Level 1 PSG study or other further investigations (depending on clinical features)
Level 3	AHI shows no OSA and data recording is adequate. Pursue further investigations for other causes of SDB.	AHI shows positive OSA diagnosis: Treat according to OSA severity and other clinical features (CPAP, or non-CPAP management)	Equipment failure or inadequate sleep – repeat study	Data available but cannot rule in nor rule out OSA – refer for Level 1 PSG study

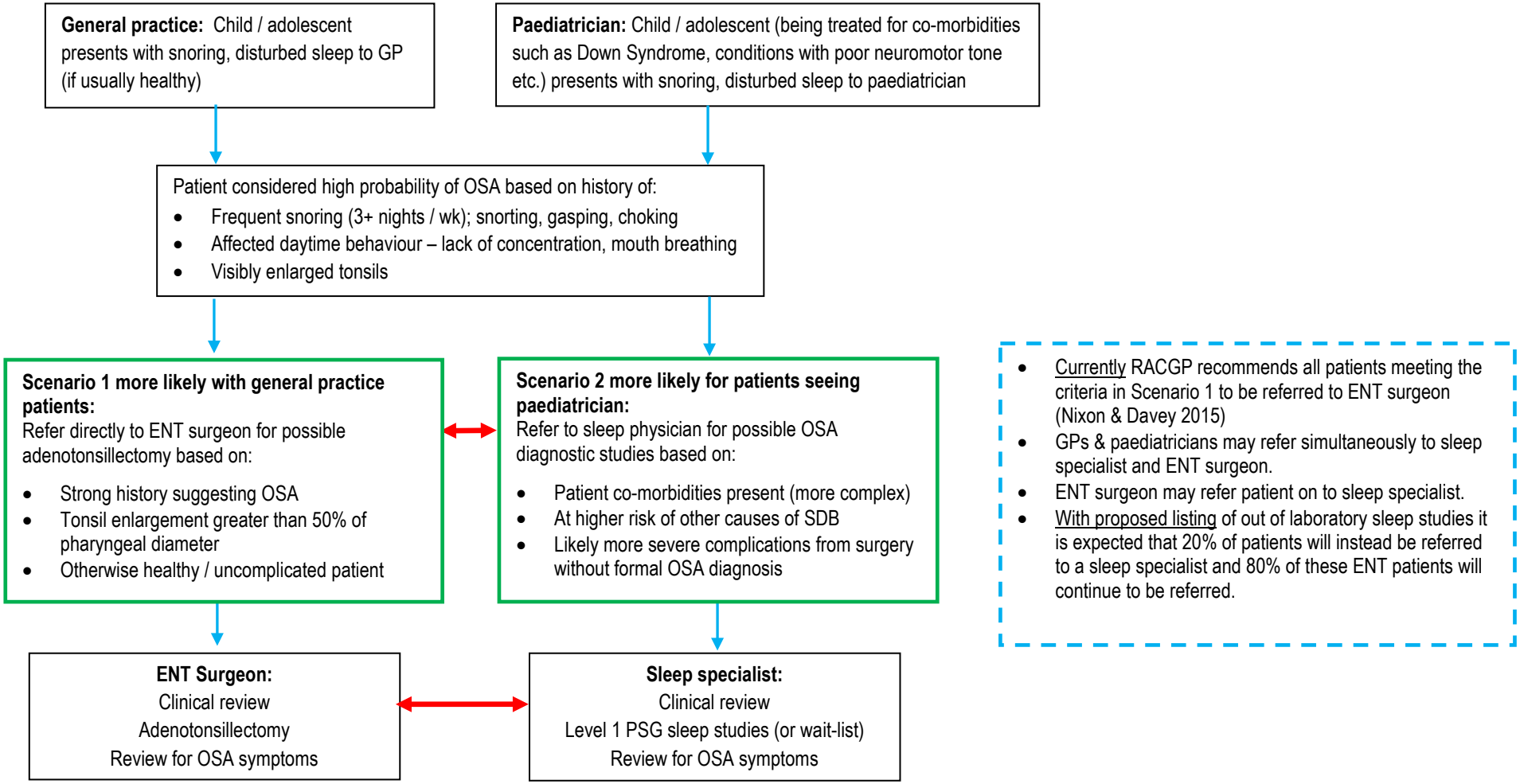
Abbreviations: AHI=apnoea / hypopnea index; CPAP=continuous positive airway pressure; OSA=obstructive sleep apnoea; SDB=sleep disordered breathing.

Table 13 Summary of changes in management – monitoring of OSA patients stable on breathing support

Study Type	Deterioration of OSA	No change in OSA	Improvement / resolution of OSA	Failed study	Inconclusive result
Level 3	Adjust CPAP/BiPAP settings and repeat after appropriate duration.	Maintenance of stability. Continue with monitoring at specified intervals. CPAP/BiPAP settings unchanged.	Adjust CPAP/BiPAP settings and repeat after appropriate duration. Or trial discontinuation of CPAP/BiPAP settings.	Repeat study or refer for Level 1 PSG study.	Investigate further. Refer for Level 2 or Level 1 PSG study.

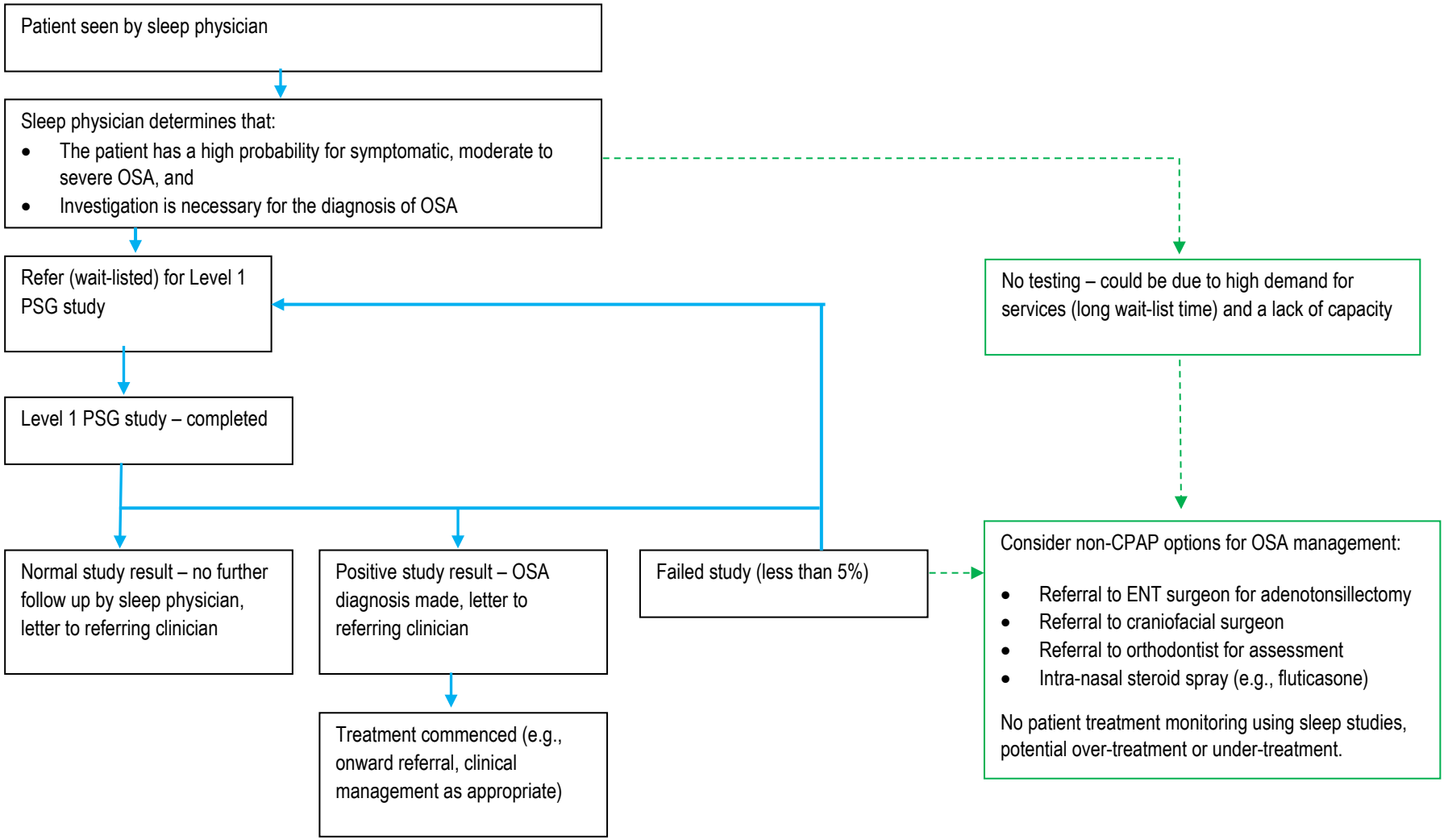
Abbreviations: BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ENT=ear, nose & throat; OSA=obstructive sleep apnoea.

Figure 2 Current management of suspected OSA paediatric cases in primary care.



Abbreviations: BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ENT=ear, nose and throat; GP=general practitioner; OSA=obstructive sleep apnoea; PSG=polysomnography, RACGP=Royal Australian College of General Practitioners; SDB=sleep disordered breathing.

Figure 3 Current management of suspected OSA paediatric cases by sleep specialists.



Abbreviations: BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ENT=ear, nose and throat; OSA=obstructive sleep apnoea; PSG=polysomnography.

PASC recalled that a significant number of questions and issues had been raised regarding the clinical algorithms at the August 2022 PASC meeting. PASC noted that most of the issues had been addressed by the applicant and agreed that the clinical algorithms appropriately reflect the current and proposed management pathways for out-of-laboratory sleep studies in paediatric and adolescent patients.

Proposed economic evaluation

The application did not provide any discussion of the proposed economic evaluation. Given the application claimed that out-of-laboratory sleep studies are non-inferior to a Level 1 PSG study, it would be reasonable to assume a cost-minimisation analysis will be provided, as outlined in Table 16.

PASC noted that the application claimed that Level 2 and 3 studies are non-inferior to a Level 1 PSG study and therefore it would be reasonable to assume that a cost-minimisation analysis would be provided. PASC noted that a claim of non-inferiority and a cost minimisation analysis would not be appropriate where 'no testing' is the comparator. PASC noted the proposed clinical claim and economic evaluation where 'no testing' is the comparator remained unresolved and requires further discussion with the applicant out of session.

Following the December 2022 PASC meeting, the revised clinical claims based on updated advice from the applicant are:

The applicant's clinical claim is that:

- Level 2 PSG study is non-inferior to Level 1 PSG in children aged 3 to <12 and adolescents aged 12 to <18 years at risk for significant OSA (PICO set 1).
- Level 3 cardiorespiratory study (diagnostic) is superior to no sleep study and standard non-CPAP management in children aged 3 to <12 and adolescents aged 12 to <18 years at risk for significant OSA and intolerant or likely to be intolerant of head leads in full for PSG setup (PICO set 2).
- Level 3 cardiorespiratory study (monitoring) is non-inferior to Level 1 PSG in children aged 3 to <12 and adolescents aged 12 to <18 years who are stable on CPAP or BiPAP respiratory support (PICO set 3).

Based on these claims (and per Table 16), the appropriate a cost-minimisation analysis comparing Level 2 PSG versus Level 1 PSG and comparing Level 3 cardiorespiratory (monitoring) versus Level 1 PSG may be reasonable. Based on the claim that Level 3 cardiorespiratory study (diagnostic) is superior to no sleep study and standard non-CPAP management, a cost-effectiveness analysis or cost-utility analysis would be appropriate.

Table 14 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

Abbreviations: CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis
[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations
[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

Proposal for public funding

Proposed items

A summary of the proposed items for MBS listing, including fees and frequency, is given in Table 17.

Table 15 Proposed MBS sleep study items (including fees and frequency)

#	Age	Study Type	Requested Fee	Adult Fee	Purpose	Maximum Frequency
Diagnostic						
1	3 ≤12 yr	Level 2	$512.96	$354.45	Investigation / diagnosis of suspected OSA in children	3 per 12 mo
2	12 ≤18 yr	Level 2	$461.63	$354.45	Investigation / diagnosis of suspected OSA in adolescents	3 per 12 mo
3	3 ≤12 yr	Level 3	$381.00	N/A	Investigation / diagnosis of suspected OSA in children unlikely to tolerate head leads	3 per 12 mo
4	12 ≤18 yr	Level 3	$381.00	N/A	Investigation / diagnosis of suspected OSA in adolescents unlikely to tolerate head leads	3 per 12 mo
Monitoring						
5	3 ≤12 yr	Level 3	$381.00	N/A	Follow-up (monitoring) in a child with diagnosed OSA	3 per 12 mo
6	12 ≤18 yr	Level 3	$381.00	N/A	Follow-up (monitoring) in an adolescent with diagnosed OSA	3 per 12 mo

Abbreviations: MBS=Medicare Benefits Schedule; mo=month; OSA=obstructive sleep apnoea; yr=year.

At the August 2022 meeting, PASC considered that for the proposed Level 3 cardiorespiratory study, two MBS items were required for the different age groups (children and adolescents) and also separate MBS items were required for diagnostic and monitoring purposes. This is now reflected in items proposed – see Table 17.

PASC noted the proposed MBS item descriptors had been modified to address PASC's feedback from the August 2022 meeting.

The applicant proposed that only NATA accredited paediatric sleep laboratories should be eligible as providers of these services in order to manage quality requirements specific to paediatric studies (see discussion about manual scoring under Proposed fees (p32). If NATA accreditation is required, the MBS listing of paediatric sleep study items could be accompanied by a note regarding accreditation requirements along similar lines to those for pathology and diagnostic imaging services (see notes IN.0.4 and PN.8.2, respectively). This would also simplify the item descriptor text.

For children aged 3 to <12 years, the proposed MBS items can be used by clinicians qualified in paediatric sleep medicine by the Royal Australasian College of Physicians (RACP) and are on the clinician list with a paediatric sleep laboratory accredited by the joint ASA and National Association of Testing Authorities (ASA/NATA) Sleep Disorders Service Accreditation Program.

For children/adolescents aged 12 to <18 years, the proposed MBS items may be used by clinicians qualified in either paediatric or adult sleep medicine by RACP and are on the clinician list with a paediatric or adult sleep laboratory accredited by the ASA/NATA Sleep Disorders Service Accreditation Program for this age group.

PASC questioned the requirement for NATA accreditation for out-of-laboratory sleep studies in children when this is not required for out-of-laboratory sleep studies in adults. The applicant clarified that while sleep studies for adults can be automatically analysed, the software is not validated for automatically analysing sleep studies in children and therefore NATA accreditation was specified as a requirement for out-of-laboratory sleep studies for children to ensure appropriately trained staff are manually interpreting the sleep study data. The applicant also confirmed that NATA accreditation would cover the home environment for out-of-laboratory sleep studies.

Proposed descriptor text

Due to number of items and length, proposed item descriptors are presented in the **Appendix D, E & F**:

- Level 2 PSG study – Item descriptor – PICO Set 1, p41
- Level 3 cardiorespiratory study (diagnostic) – Item descriptors – PICO Set 2, p43
- Level 3 cardiorespiratory study (monitoring) – Item descriptors – PICO Set 3, p45

Proposed fees

The fees requested by the applicant are summarised in Table 17. The proposed MBS fees for Level 2 PSG studies for children ($512.96) and adolescents ($461.63) differ from the current fee for adult Level 2 PSG studies ($354.45).

At the August 2022 PASC meeting, PASC considered that the proposed item fees should be revised and exclude costs not covered by the MBS (e.g., equipment, consumables, courier, travel etc). These cannot be claimed in the MBS fee, and therefore the proposed fee is likely overestimated. PASC (August 2022) also considered that further justification is required for the fee discrepancy among different age groups for the same tests (e.g., Level 2 PSG paediatric item fee is $512.96 vs Level 2 PSG adolescent item fee $461.63). PASC (August 2022) also noted that the proposed MBS fees for Level 2 PSG studies for children (paediatric and adolescent) are higher than the adult Level 2 PSG study (MBS item number 12250).

The post-PASC advice from the applicant (following the August 2022 PASC meeting) noted that studies for paediatric patients take more time and skill to manage – in particular, all data must be fully manually scored, as automatic scoring (used to assist adult studies) is not accurate for these patients. The applicant further advised that full manual scoring is a requirement of quality systems for paediatric sleep laboratory

NATA accreditation. The additional scoring effort is the basis for the claimed cost differential between adult versus paediatric item fees. Existing MBS items for adult sleep studies refer to manual scoring, but this is assisted by computerised scoring, using algorithms which lead to higher rates of false negatives in paediatric patients. The applicant stated sleep studies involving children younger than 13 require more staff time and resources to administer than sleep studies for adolescents. This is reflected in the higher fees for Level 1 PSG studies for children aged <12 years of age (MBS item 12210, fee $742) versus adolescents aged 12 - <18 years of age (MBS item 12213, fee $668.45).

PASC recalled from the August 2022 meeting, that PASC had previously considered that the proposed fees were likely overestimated and PASC had advised that the proposed item fees should be revised and exclude items not covered by the MBS (e.g., equipment, consumables, courier, car etc). However, PASC noted that the fees had not been revised and that the applicant had not provided a detailed breakdown or justification for the proposed MBS fees for the sleep studies.

PASC noted that the proposed fees for Level 2 sleep studies and the current MBS fees for Level 1 sleep studies vary depending on age group, with higher fees for studies in children and adolescents than adults. The applicant explained that paediatric studies take longer and require increased expertise as a consequence of multiple factors (for example, more support and attention required for paediatric vs adolescent patients; increased burden of managing leads and attached equipment in children compared to adults) regardless of whether the study is performed in a laboratory or at home. PASC considered evidence to support these claims would need to be provided and that revision of the fees, along with provision of a detailed breakdown and justification for the fees remained an unresolved issue for the applicant to address.

Following the December 2022 PASC meeting, the applicant provided further information. This information will be reviewed and incorporated into the economic and financial analysis undertaken during the evaluation phase.

PASC queried the funding of additional costs associated with out-of-laboratory sleep studies (such as consumables, equipment, courier, travel, etc.) and whether these costs would fall to the patient. The Department cited data relating to the MBS item for out-of-laboratory sleep studies in adults (item 12250), confirming that patients incur out-of-pocket costs of around $[redacted].

Following the December 2022 PASC meeting, the applicant responded that out-of-pocket costs may be borne by the patient or the sleep laboratory. The applicant asserted that there is no standard approach to these additional costs and amounts would vary. The applicant suggested that most public hospitals will absorb additional costs.

Proposed frequency

The applicant has proposed a frequency restriction of three services per 12 months for Level 2 PSG and Level 3 cardiorespiratory studies (both diagnostic and monitoring)(Table 16). At the August 2022 meeting, PASC considered further clarification was needed on the number of times an item can be claimed; whether three services in 12 months was appropriate given the limits on study performance and the need for repeat studies, and whether an item can be co-claimed with other items. However, PASC (August 2022) suggested to first refine the clinical algorithm with the use of sleep studies to be based on purpose.

A maximum of two sleep studies every 12 months per proposed item may be appropriate in most cases, noting the following:

- For PICO Set 1 (Level 2 PSG study), allowing for two initial out-of-laboratory PSG studies, it is plausible that any further sleep studies would either be in-laboratory (for further investigation, or titration) or Level 3 cardiorespiratory (for monitoring).

- For PICO Set 2 (Level 3 cardiorespiratory study for diagnosis), challenging patients may need to repeat the sleep study, at least two studies may be required in the first instance for a subset of patients without including any follow-up investigations using the same item.
- For PICO Set 3 (Level 3 cardiorespiratory study for monitoring), a maximum of at least two studies within 12 months appears reasonable in order to achieve review intervals of 6-12 months.
- Titration of CPAP/BiPAP must use a Level 1 PSG in children and adolescents; other further investigations would also often be Level 1 PGS studies – these would be claimed under the in-laboratory items.
- A subset of patients with complex features may require repeated or further investigations, but it is assumed they would only have in-laboratory studies (or at least after initial testing).
- Thus, a plausible limit could be a maximum of three claims under any of the paediatric out-of-laboratory items in a 12-month period. An exception could be patients who have had repeat studies for diagnosis, followed by monitoring within a 12-month period, where this could plausibly be four studies.

Summary of public consultation input

Consultation feedback received for August 2022 PASC meeting (1st consideration)

Consultation feedback was received from one professional organisation, the Thoracic Society of Australia and New Zealand (TSANZ), for consideration at the August 2022 PASC meeting. The consultation feedback was largely supportive of the application.

TSANZ stated that public funding of this service will decrease waiting times for services which have lower cost than laboratory studies and noted that home-based sleep studies are being utilised in well-defined settings in the UK. They added that it may also improve access to diagnosis and treatment for children living distant from accredited laboratories. They further stated that the proposed service will improve diagnostic capability in children with low tolerance for laboratory conditions.

The consultation feedback did not identify any significant disadvantages of public funding. However, TSANZ highlighted the following issues with out-of-laboratory sleep studies:

- TSANZ noted high failure rates and the need for repeat studies.
- There is a need for monitoring the use of out-of-laboratory sleep studies, as clinical decisions would be made based on suboptimal monitoring, especially for Level 3 and 4 studies.
- Potential for unnecessary or excessive use of sleep studies.
- Due to the difference in the diagnostic criteria for OSA for children (AHI > 1/h) compared to adults (AHI > 5/h), this could lead to a disparity in the diagnosis of OSA in an adolescents (12-18 yr age group) depending on whether the out-of-laboratory sleep study is done by paediatric and adult sleep physician/sleep laboratory, which potentially could result in under diagnosis of sleep disordered breathing in children aged 12-18 years.
- Commercialisation of the home sleep service by the private sector.

TSANZ included that only paediatric sleep specialists accredited in Australia should be allowed to request and report the proposed service. They also added that children with failed studies at home may need a repeat study or attend a hospital-based study.

TSANZ suggested extending the overnight pulse oximetry eligibility criteria to include children 12-18 years of age and living in metropolitan areas. TSANZ also suggested clarification of the calculations for the costs of both the equipment required for oximetry in Level 4 studies and the travel of sleep scientists.

Consultation feedback received for December PASC meeting (2nd consideration)

Following the August 2022 PASC meeting, the Department requested further targeted consultation and input was received from the Australian Society of Otolaryngology Head and Neck Surgery (ASOHNS). The feedback from ASOHNS helped inform further development of the clinical algorithms. In addition, consultation feedback was received from 1 professional organisation and 1 consumer organisation for consideration at the December 2022 PASC meeting. The organisations that submitted input were:

- Australia and New Zealand Sleep Science Association (ANZSSA)
- Sleep Health Foundation (SHF).

The consultation feedback received was supportive of public funding for the application.

- The main benefits of public funding received in the consultation feedback included:
    - Benefits of improved access to sleep studies such as health equity, provision of a wide ranging and more comprehensive service, and the provision of services in both metro and regional areas.
    - Improved wellbeing for children and their families, including relief of anxiety relating to hospital attendance for both caregivers and patients, reduced burden on patients and families, elimination of travel and associated costs, decreased wait times, earlier diagnosis, and potential for improved data acquisition in children known to have low tolerance for in-hospital conditions.
    - Benefits for sleep and ENT physicians, allowing them to triage surgery based on clinical need, allows specialists to gain insight into post-operative risk and allow at-risk children to be appropriately provided a higher level of post-operative care, as well as potentially reducing morbidity and mortality associated with adenotonsillectomy.
- The main disadvantages of public funding received in the consultation feedback included:
    - Disadvantages associated with remote monitoring such as increased rate of signal loss, elevated risk of false negative diagnosis, and risk of entanglement in the leads.

ANZSSA stated they had concerns regarding the wording of phone or video link in Level 4 studies and that they do not believe funding should be requisite on phone or video teleconferencing during application of the oximeter probe to the child. ANZSSA further stated that the overall success rate of drive-through Level 4 studies performed at the Monash Children's Sleep Centre during the COVID-19 pandemic (n=388) was 96.4%, despite only written materials, a link to an instructional video, and a support telephone number being provided to parents and carers. ANZSSA stated that they anticipate the risk of signal loss or study failure will be mitigated by testing being restricted to NATA/ASA accredited services with the addition of telephone support.

ANZSSA stated that with regards to the treatment monitoring population, using data from respiratory support units (e.g. CPAP or BiPAP) in place of sleep studies provides insufficient information. These patients require a level 3 or 4 study to adequately monitor their treatment (e.g. CPAP or BiPAP) and this population would have better access to these studies if out-of-laboratory studies were publicly funded.

ANZSSA stated they support the proposed medical service and clinical claim, main comparator and cost for the proposed service, noting that:

- Funding should only be available for studies requested by paediatric or adult sleep physicians from a NATA accredited facility.
- The proposed fees are appropriate given the need for (1) secure postage and handling of medical equipment and onboard patient data, (2) processing of equipment (cleaning) and acquired data,

(3) clinician time reporting on acquired data, (4) ongoing equipment maintenance and repair, and (5) quality assurance.

PASC noted the consultation feedback from the Thoracic Society of Australia and New Zealand (TSANZ), both the feedback received prior to the previous August 2022 PASC meeting and the subsequent responses to the targeted consultation questions from PASC. PASC also noted more recent feedback from the Australian Society of Otolaryngology, Head and Neck Surgery (ASOHNS), the Australian New Zealand Sleep Science Association (ANZSSA), and the Sleep Health Forum (community group).

Next steps

The applicant confirmed that the assessment should proceed as a Department Contracted Assessment Report (DCAR).

Applicant comment on the PICO confirmation

In Table 7 and the population description for PICO set 2, the "5% of patients likely to find head leads distressing or challenging" relates to the patient group in whom this sensitivity would likely lead to a complete study failure. Lanzlinger et. al. 2023 is a new reference relating to PSG tolerance in neuro diverse children.

References

Baker-Smith, C.M., et al., Sleep-Disordered Breathing and Cardiovascular Disease in Children and Adolescents: A Scientific Statement From the American Heart Association. J Am Heart Assoc, 2021. 10(18): p. e022427.

British Thoracic Society (BTS). BTS Guideline for diagnosing and monitoring paediatric sleep disordered breathing. Draft for public consultation. February 2022.

Chawla, J., et al., Ventilatory support at home for children: A joint position paper from the Thoracic Society of Australia and New Zealand/Australasian Sleep Association. Respirology, 2021. 26(10): p. 920-937.

Gozal, D., L. O'Brien, and B.W. Row, Consequences of snoring and sleep disordered breathing in children. Pediatr Pulmonol Suppl, 2004. 26: p. 166-8.

Griffiths, A., A. Mukushi, and A. Adams, P043 Telehealth-supported Level 2 paediatic home polysomnography. SLEEP Advances, 2021. 2. p. A35.

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. J Clin Sleep Med. 2020 Jul 15;16(7):1013-1019.

Jacob SV, Morielli A, Mograss M, et al. Home testing for pediatric obstructive sleep apnea syndrome secondary to adenotonsillar hypertrophy. Pediatr Pulmonol 1995;20:241-52.

Katz, E.S. and C.M. D'Ambrosio, Pathophysiology of pediatric obstructive sleep apnea. Proc Am Thorac Soc, 2008. 5(2): p. 253-62.

Lanzlinger, D., Kevat, A., Collaro, A., Poh. S.H., Pérez, W. and Chawla. J. Tolerance of polysomnography in children with neurodevelopmental disorders compared to neurotypical peers. J Clin Sleep Med. 2023 Apr doi.org/10.5664/jcsm.10626

Liu CC, Chaput KH, Kirk V, Yunker W. Overnight oximetry in children undergoing adenotonsillectomy: a single center experience. J Otolaryngol Head Neck Surg. 2019 Dec 3;48(1):69.

Lumeng, J.C. and R.D. Chervin, Epidemiology of pediatric obstructive sleep apnea. Proceedings of the American Thoracic Society, 2008. 5(2): p. 242-252.

Marcus, C.L., et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics, 2012. 130(3) : p.576–84.

Nixon, Gillian M and Davey, Margot. Sleep apnoea in the child. Australian Family Physician, Volume 44, Issue 6, June 2015.

Pamula, Y., et al., Australasian Sleep Association clinical practice guidelines for performing sleep studies in children. Sleep Med, 2017. 36 Suppl 1: p. S23-s42.

Pavone M, Ullmann N, Verrillo E, De Vincentiis G, Sitzia E, Cutrera R. At-home pulse oximetry in children undergoing adenotonsillectomy for obstructive sleep apnea. European Journal of Pediatrics. 2017. 176:493-499.

Poels PJ, Schilder AG, van den Berg S, et al. Evaluation of a new device for home cardiorespiratory recording in children. Arch Otolaryngol Head Neck Surg 2003;129:1281-4.

Russo, K., J. Greenhill, and S. Burgess. Home (Level 2) polysomnography is feasible in children with suspected sleep disorders. Sleep Med, 2021. 88: p. 157-161.

Scalzitti N, Hansen S, Maturo S, Lospinoso J, O'Connor P. Comparison of home sleep apnea testing versus laboratory polysomnography for the diagnosis of obstructive sleep apnea in children. Int J Pediatr Otorhinolaryngol. 2017 Sep;100:44-51.

Tan HL, Kheirandish-Gozal L, Gozal D. Pediatric Home Sleep Apnea Testing: Slowly Getting There! Chest. 2015 Dec;148(6):1382-1395.

Twiss J, Chawla J, Davey MJ, Edwards EA, Elder D, Francis A, Griffiths A, Pamula Y, Suresh S, Verginis N, Nixon GM. Overnight Oximetry for evaluating Paediatric Obstructive Sleep Apnoea. Australasian Sleep Association. March 2016.

Appendix

Appendix A - Paediatric sleep study MBS claims data

Level 1 PSG sleep study services (MBS items 12210 + 12213) grouped by patient location for the 2021-2022 financial year are provided in Table 18. [redacted]

Table 16 MBS Claims data – paediatric Level 1 PSG studies by MM location (2021 – 2022 FY)

Modified Monash Model Location	Claims	Proportion	MM2 – MM7 Claims
MM1	[redacted]		
MM2			[redacted]
MM3			
MM4			
MM5			
MM6			
MM7			
Total	**6,586**	**100%**	**1,276**

Source: MBS data provided by the Department, table compiled for this PICO Confirmation.

Appendix B - PASC comments from August 2022 meeting

Level 3 cardiorespiratory studies

PASC queried whether there are any other clinical indications that require a Level 3 cardiorespiratory study instead of a Level 2 PSG study. PASC considered that clarification from the applicant was needed on the clinical criteria for choosing the correct population for diagnosing OSA using a Level 3 cardiorespiratory study as opposed to a Level 2 PSG study.

PASC considered that ECG monitoring should be listed as a channel for the Level 3 cardiorespiratory study item descriptor. PASC noted that Level 3 cardiorespiratory studies have significant false negative rates and failed tests. PASC noted the pre-PASC response suggested that 10% of Level 3 cardiorespiratory studies would be inconclusive or incomplete. However, feedback from TSANZ suggested that the Level 3 cardiorespiratory study failure rate (thus needing repeat studies) was 13-26%, with a sensitivity of 61-91% and specificity of 16-93%, meaning higher false positive rates, leading to potentially inappropriate treatment, compared to Level 1 and 2 PSG study. PASC considered that clarification was required on the estimate of failed tests (inclusive of technical failures, inadequate data or inconclusive tests). PASC also queried whether a Level 3 cardiorespiratory study was adequate at all as a stand-alone test to diagnose OSA. That is, can a Level 3 cardiorespiratory study reliably rule out OSA given the test has a significant false negative rate, or is a Level 3 cardiorespiratory study used for triaging patients for a Level 1 PSG study. PASC also noted the application indicated that following a failed Level 3 cardiorespiratory study, the patient will require a repeat testing with a Level 1 PSG study. PASC queried whether the repeat study could be a Level 2 study and confirmation will need to be sought from the applicant regarding this.

Level 4 pulse oximetry studies

PASC noted the Level 4 oximetry study consisted of single lead oximetry only and measures a single parameter e.g., oxygen saturation and heart rate. PASC considered clarification is required regarding the clinical indications for a Level 4 oximetry study, the diagnostic accuracy and limitations of a Level 4 oximetry study, and how it would change clinical management. PASC noted that a high proportion (70%) of results are inconclusive, and questioned whether these rural/regional patients are better served with a Level 2 PSG study instead of a Level 4 oximetry study. PASC considered clarification is needed on whether the inconclusive rate of 70% includes both negative results as well as uninterpretable studies. PASC noted it was unclear whether patients with inconclusive oximetry results, who require repeat testing, will subsequently go on to be waitlisted for a Level 1 or a Level 2 PSG study. PASC noted this would mean additional wait times, thus not impacting the issue of access to services in rural and regional areas. PASC was also uncertain whether a Level 4 oximetry study would be used as a 'rule in' test for access to treatment, referral to ENT surgery and/or determining the location for surgery according to risk for post-operative complications or whether the Level 4 oximetry study would be used as a prior test to triage patients for a Level 1 PSG study. PASC queried whether patients would then wait for a Level 1 PSG study or be referred directly for surgery given the long wait times for Level 1 PSG studies. PASC also queried whether there is any role for Level 4 oximetry sleep studies in patients with clinically obvious adenotonsillar hypertrophy given the decision to operate can be made on physical examination and clinical opinion. PASC considered that further advice should be sought from ENT surgeons on this issue.

PASC also indicated further clarification was needed around terminology such as inconclusive result and technical failure. That is, what constitutes an inconclusive result and is it the same for each study level, i.e., does it include negative result, uninterpretable, incomplete due to technical failure etc. Further, what constitutes a technical failure, is it leads falling off, an inconclusive result and/or inadequate data.

Appendix C - Equipment for out-of-laboratory sleep studies

Table 17 Medical devices currently registered / used in Australia for home sleep studies

Device	Description	Sleep study
Somte PSG	Manufacturer: Compumedics TGA approved device: Yes (ARTG 198298) Equipment for Level 2 PSG study: Somte PSG recorder and input box • Pulse oximeter probe (paediatric and adult sizes) • Respiratory bands • Electrodes: ECG, chin, head leads, eye leads, ground, leg leads • Nasal cannula and Thermistor • Position sensor • Profusion PSG (software) Current use in clinical practice*: Used for paediatric home sleep studies by groups in Melbourne and Perth. Used for adult out-of-laboratory sleep studies in Australia for MBS item 12250 studies (Level 2 PSG studies).	Level 2
Somnotouch	Manufacturer: Somnomedics TGA approved device: Yes (ARTG 343713) Equipment for Level 2 PSG study: Somnotouch sleep screener plus software (BHCTOR105) • Somnotouch AASM headbox (BHCTOS095) • Belt set (paediatric and adult sizes) • ECG lead • SpO_2 silicone finger probe (paediatric and adult sizes) • Grass Gold cup electrodes and 2 leg leads • Nasal canula • Docking station Current use in clinical practice*: Not currently used in Australia in paediatrics. However, used widely in the United Kingdom and some Europeans centres.	Level 2 or 3
Nox A1 and Nox T3	Manufacturer: Nox medical TGA approved: Yes (ARTG 232041) Equipment for Level 2 PSG study: Nox A1 device (NX563010) • Noxturnal (software) • Nox RIP belts (paediatric, small, medium and large sizes) • Paediatric EEG bundle and chin leads • ECG cable • 2 leg leads • Paediatric cannula and paediatric thermistor (latter optional) • Wrist Ox2 sensors (small, medium and large sizes) Current use in clinical practice*: Used for paediatric home sleep studies by Brisbane group. Used for in-patient studies by several Australian labs.	Level 2 (A1) or 3 (T3)
Masimo Radical-7 oximeter	Manufacturer: Masimo Australia TGA approved: Yes (ARTG 157479)	All levels
Radiometer TCM5 basic and flex monitors	Supplier: Radiometer Pacific TGA approved: Yes (ARTG *not provided)*	Level 2, 3 and 4
Medtronics Nellcor oximeter	Supplier: Medtronic Australasia TGA approved: Yes (ARTG *not provided)*	All levels
Sentec Oxicapnograph	Supplier: Temple Healthcare TGA approved: Yes (ARTG *not provided)* Combined transcutaneous carbon dioxide and oxygen with pulse oximeter oxygen saturation monitor	All levels

Source: pp6-8 of 1712 Application Form.docx

Abbreviations: ARTG – Australian Register of Therapeutic Goods; ECG – electrocardiogram; EEG – electroencephalogram; PSG – polysomnography; RIP – respiratory inductance plethysmography; SpO_2 – peripheral oxygen saturation; TGA – Therapeutic Goods Administration.

* Advice from the applicant

Appendix D - Item descriptor – PICO Set 1

Table 18 Applicant proposed MBS item descriptors for Level 2 PSG studies

Category 2: Diagnostic Procedures and Investigations
MBS item XXXX Overnight investigation of sleep for at least 8 hours of a patient aged 3 to <12 years to confirm diagnosis of obstructive sleep apnoea, if: (i) the patient has been referred by a general practitioner to a qualified paediatric sleep medicine practitioner who has determined that the patient has a high probability of symptomatic, moderate to severe obstructive sleep apnoea; and (ii) following professional attendance of 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 (a) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, a minimum of 7 channels that include (i) to (vii) of the following measures: (i) airflow; (ii) continuous EMG; (iii) continuous ECG; (iv) continuous EEG; (v) EOG; (vi) oxygen saturation; (vii) respiratory effort (viii) ~~+/-~~ (optional) measurement of carbon dioxide (either end tidal or transcutaneous);~~ - this to be assessed on case by case basis by paediatric sleep medicine specialist.~~ (b) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner who is listed on staff of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program; and (c) either: (i) ~~the equipment is applied to the patient by a paediatric sleep professional [scientist, technician, nurse, or doctor listed on the staff list of an accredited paediatric sleep laboratory] either at the laboratory or at the patients' place of residence; or~~the equipment is applied to the patient by a sleep technician; or (ii) ~~if child lives > 50km from an accredited paediatric sleep laboratory by a health professional who has been trained in the application of leads by staff from an accredited paediatric sleep laboratory ; and is listed as an associate clinical staff member of the accredited sleep laboratory and thus will participate in laboratory in-house education to maintain skills~~if this is not possible - the reason it is not possible for the accredited paediatric sleep laboratory professional to apply the equipment to the patient is documented and a health professional is given instructions on how to apply the equipment by an affiliated accredited paediatric sleep laboratory. (d) written instructions are given to parent/caregiver to monitor the child overnight and a phone contact or data link to the accredited paediatric sleep laboratory to enable trouble shooting overnight if required; and (e) 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 (f) interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist who is listed on staff of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program with personal direct review of raw data from the original recording of polygraphic data from the patient; and (g) 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 For each particular patient, up to a maximum of three services across all out of laboratory sleep study types will be applicable in any 12 month period. ~~Applicable only twice in any 12-month period~~
Fee: $512.96
MBS item XXXX Overnight investigation of sleep for at least 8 hours of a patient aged 12 to <18 years to confirm diagnosis of obstructive sleep apnoea, if:

(i) the patient has been referred by a medical practitioner to a qualified paediatric or adult sleep medicine practitioner who has determined that the patient has a high probability of symptomatic, moderate to severe obstructive sleep apnoea; and

(ii) following professional attendance of 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

(a) during a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures:

(i) airflow;

(ii) continuous EMG;

(iii) continuous ECG;

(iv) continuous EEG;

(v) EOG;

(vi) oxygen saturation;

(vii) respiratory effort;

(viii) ~~+/-~~ (optional) measurement of carbon dioxide (either end tidal or transcutaneous); ~~- this to be assessed on case by case basis by paediatric or adult sleep medicine specialist:~~ and

(b) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner [who is listed on the staff list of a NATA/ASA accredited sleep laboratory]; who has determined if CO2 recording is required and

(c) either:

(i) ~~the equipment is applied to the patient by an paediatric or adult sleep professional [scientist, technician, nurse or doctor] who is listed on the staff list of a NATA/ASA accredited sleep laboratory either at the laboratory or at the patients place of residence; or~~ the equipment is applied to the patient by a sleep technician; or

(ii) ~~if child lives > 50km from an accredited paediatric or adult sleep laboratory from an accredited sleep laboratory by a health professional who has been trained in the application of leads by staff from an accredited paediatric sleep laboratory; and is listed as an associate clinical staff member of the accredited sleep laboratory and thus will participate in laboratory in-house education to maintain skills.~~ if this is not possible - the reason it is not possible for the accredited paediatric sleep laboratory professional to apply the equipment to the patient is documented and a health professional is given instructions on how to apply the equipment by an affiliated accredited paediatric sleep laboratory.

(d) written instructions are given to parent/caregiver to monitor the child overnight and a phone contact or data link to the accredited paediatric or adult sleep laboratory to enable trouble shooting overnight if required.

(e) polygraphic records are:

(i) analysed (for assessment of sleep stage, arousals, respiratory events and cardiac abnormalities) with 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

(f) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine specialist [who is on staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of polygraphic data from the patient; and

(g) 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 is provided to the patient

For each particular patient, up to a maximum of three services across all out of laboratory sleep study types will be applicable in any 12 month period.

~~Applicable only twice in any 12-month period~~

Fee: $461.63

Source: pp51-53 of 1712 Application Form.docx.
Suggested additions underlined and deletions in strikethrough are presented by the evaluators and the Department.
Abbreviations: ASA = Australasian Sleep Association; CO2 = carbon dioxide; CPAP = continuous positive airway pressure; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram NATA = National Association of Testing Authorities

Appendix E - Item descriptors – PICO Set 2

Table 19 Department proposed MBS item descriptors for Level 3 cardiorespiratory study (diagnostic)

Category 2: Diagnostic Procedures and Investigations
MBS item XXXX Overnight investigation of sleep for at least 8 hours of a patient aged 3 to <12 years to confirm diagnosis of obstructive sleep apnoea, if: (i) The patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea and is non tolerant of head leads when full PSG attempted; and (ii) following professional attendance of 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 (a) During a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures: i) airflow; ii) oxygen saturation; iii) respiratory effort; iv) ECG or heart rate* v) ~~+/-~~ (optional) measurement of carbon dioxide (either end tidal or transcutaneous); ~~this to be assessed on case by case basis by paediatric sleep medicine specialist~~ (b) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner [who is listed on the staff list of a NATA/ASA accredited sleep laboratory]; who has determined if CO2 recording is required and (c) 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 accredited paediatric sleep laboratory professional to apply the equipment to the patient is documented and a health professional is given instructions on how to apply the equipment by an affiliated accredited paediatric sleep laboratory. (d) The parents/caregivers are instructed on how to check recording is occurring and to trouble shoot loss of leads. They are given a contact number/data link for overnight support with recording. *(e)* Polygraphic records are: (i) analysed for assessment of respiratory events and cardiac abnormalities with 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 (f) Interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist [who is listed on staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of polygraphic data from the patient; ~~al~~ and (g) 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 For each particular patient, up to a maximum of three services across all out of laboratory sleep study types will be applicable in any 12 month period.
Fee: $381

MBS item XXXX

Overnight investigation of sleep for at least 8 hours of a patient aged 12 to <18 years to confirm diagnosis of obstructive sleep apnoea, if:

(i) The patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea and is non tolerant of head leads when full PSG attempted; and

(ii) following professional attendance of 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

(a) During a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures:

i) airflow;

ii) oxygen saturation;

iii) respiratory effort;

iv) ECG or heart rate*

v) ~~+/-~~ (optional) measurement of carbon dioxide (either end tidal or transcutaneous); ~~this to be assessed on case by case basis by paediatric sleep medicine specialist~~

(b) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner [who is listed on the staff list of a NATA/ASA accredited sleep laboratory]; who has determined if CO2 recording is required and

(c) 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 accredited paediatric sleep laboratory professional to apply the equipment to the patient is documented and a health professional is given instructions on how to apply the equipment by an affiliated accredited paediatric sleep laboratory.

(d) The parents/caregivers are instructed on how to check recording is occurring and to trouble shoot loss of leads. They are given a contact number/data link for overnight support with recording.

(e) Polygraphic records are:

(i) analysed for assessment of respiratory events and cardiac abnormalities with 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

(f) Interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist [who is listed on staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of polygraphic data from the patient; and

(g) 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

For each particular patient, up to a maximum of three services across all out of laboratory sleep study types will be applicable in any 12 month period.

Fee: $381

Source: Adapted by the Department from pp53-54 of 1712 Application Form to present separate paediatric/adolescent diagnosis and monitoring items for Level 3 cardiorespiratory and to include ECG as channel

Suggested additions underlined and deletions in strikethrough are presented by the evaluators and the Department.

Abbreviations: ASA = Australasian Sleep Association; CO2 = carbon dioxide; CPAP = continuous positive airway pressure; ECG = electrocardiogram; NATA = National Association of Testing Authorities

* Existing item descriptors for Level 1 and Level 2 PSG specify ECG. Previously PASC advised that ECG should be included as one of the channels for Level 3 as well. Whether it is appropriate for Level 3 item descriptor include "ECG" or "ECG or heart rate" will be assessed during the assessment phase.

Appendix F - Item descriptors – PICO Set 3

Table 20 Department proposed MBS item descriptors for Level 3 cardiorespiratory study (monitoring)

MBS item XXXX

Overnight investigation of sleep for at least 8 hours of a patient aged 3 to <12 years to confirm adequacy of present respiratory support [CPAP or bilevel], if:

(i) The patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner who has determined that the patient is stable on current respiratory support for sleep disordered breathing; and

(ii) following professional attendance of the patient (either face to face or by video conference) by a qualified paediatric sleep medicine specialist who determines that investigation is necessary to assess respiratory support therapy [CPAP or bilevel]; and

(a) During a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures:

i) airflow;

ii) oxygen saturation;

iii) respiratory effort;

iv) ECG or heart rate

v) ~~+/-~~ (optional) measurement of carbon dioxide (either end tidal or transcutaneous); ~~this to be assessed on case by case basis by paediatric sleep medicine specialist~~

(b) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner [who is listed on the staff list of a NATA/ASA accredited sleep laboratory]; who has determined if CO2 recording is required and

(c) 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 accredited paediatric sleep laboratory professional to apply the equipment to the patient is documented and a health professional is given instructions on how to apply the equipment by an affiliated accredited paediatric sleep laboratory.

(d) The parents/caregivers are instructed on how to check recording is occurring and to trouble shoot loss of leads. They are given a contact number/data link for overnight support with recording.

(e) Polygraphic records are:

(i) analysed for assessment of respiratory events and cardiac abnormalities with 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

(f) Interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist [who is listed on staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of polygraphic data from the patient; ~~al~~ and

(g) 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

For each particular patient, up to a maximum of three services across all out of laboratory sleep study types will be applicable in any 12 month period.

Fee: $381

MBS item XXXX

Overnight investigation of sleep for at least 8 hours of a patient aged 12 to <18 years to confirm adequacy of present respiratory support [CPAP or bilevel], if:

(i) The patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner who has determined that the patient is stable on current respiratory support for sleep disordered breathing; and

(ii) following professional attendance of the patient (either face to face or by video conference) by a qualified paediatric sleep medicine specialist who determines that investigation is necessary to assess respiratory support therapy [CPAP or bilevel]; and

(a) During a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures:

i) airflow;

ii) oxygen saturation;

iii) respiratory effort;

iv) ECG or heart rate

v) ~~+/-~~ (optional) measurement of carbon dioxide (either end tidal or transcutaneous); ~~this to be assessed on case by case basis by paediatric sleep medicine specialist~~

(b) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner [who is listed on the staff list of a NATA/ASA accredited sleep laboratory]; who has determined if CO2 recording is required and

(c) 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 accredited paediatric sleep laboratory professional to apply the equipment to the patient is documented and a health professional is given instructions on how to apply the equipment by an affiliated accredited paediatric sleep laboratory.

(d) The parents/caregivers are instructed on how to check recording is occurring and to trouble shoot loss of leads. They are given a contact number/data link for overnight support with recording.

(e) Polygraphic records are:

(i) analysed for assessment of respiratory events and cardiac abnormalities with 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

(f) Interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist [who is listed on staff of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of polygraphic data from the patient; ~~al~~ and

(g) 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

For each particular patient, up to a maximum of three services across all out of laboratory sleep study types will be applicable in any 12 month period.

Fee: $381

Source: Adapted by the Department from pp53-54 of 1712 Application Form to present separate paediatric/adolescent diagnosis and monitoring items for Level 3 cardiorespiratory and to include ECG as channel

Suggested additions underlined and deletions in strikethrough are presented by the evaluators and the Department.

Abbreviations: ASA = Australasian Sleep Association; CO2 = carbon dioxide; CPAP = continuous positive airway pressure; ECG = electrocardiogram; NATA = National Association of Testing Authorities

* Existing item descriptors for Level 1 and Level 2 PSG specify ECG. Previously PASC advised that ECG should be included as one of the channels for Level 3 as well. Whether it is appropriate for Level 3 item descriptor include "ECG" or "ECG or heart rate" will be assessed during the assessment phase.

Appendix G – Information specific to PICO Set 4

Table 21 PICO for out-of-laboratory sleep (Level 4 pulse oximetry) study in children and adolescents: PICO Set 4 – not progressing to the evaluation stage as part of this application

Component	Description	
Population	Children aged 1 to <12[a] and adolescents aged 12 to <18[b] years with sleep disordered breathing (SDB) that have been referred by a medical practitioner who provides a service at, or from, a practice location in: a. a Modified Monash 2 area; or b. a Modified Monash 3 area; or c. a Modified Monash 4 area; or d. a Modified Monash 5 area; or e. a Modified Monash 6 area; or f. a Modified Monash 7 area; i. to a qualified paediatric or adult[b] sleep medicine practitioner who had determined that the patient has a high probability for symptomatic, moderate to severe OSA, and ii. following professional attendance of the patient (either face-to-face or by video conference) by a qualified paediatric or adult[b] sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of OSA	
Intervention	Level 4 pulse oximetry study with a pulse oximeter in out-of-sleep-laboratory setting	
Comparator/s	Main: Level 1 or Level 2 PSG studies Secondary: • No testing, followed by ENT surgery • No testing, followed by standard non-CPAP management (not including ENT surgery)	
Reference standard	Level 1 PSG study in an accredited sleep laboratory with 12-13 recording channels routinely recorded, and trained sleep laboratory staff in attendance.	
Outcomes	Testing success	Failed test Repeat testing Referrals for Level 1 PSG studies Referrals for Level 2 PSG studies
	Technical performance	Sensitivity Specificity Positive and negative predictive values Rates of false positive and false negative results
	Change in management	Referral for ENT surgery Time from primary care referral to diagnosis
	Patient outcomes	Improvement in neurocognitive performance, and cardiorespiratory illness Sleep outcomes (measure of interrupted sleep or sleep improvement; sleep-related behavioural problems; reduction in surrogate measures e.g., obstructive AHI, desaturations) Quality of Life
	Prognostic outcome	Surgical risk (McGill score – relevant to Level 4 pulse oximetry)
	Safety	Device issues: Skin reactions and lead entanglement Nosocomial infections avoided Unplanned peri-operative emergency transfer Unplanned peri-operative intubation
	Health system outcomes	Health care utilisation Wait-list times
Assessment questions	What is the safety, effectiveness and cost-effectiveness of Level 4 pulse oximetry as a triage test for OSA versus no testing (followed by ENT surgery or by standard non-CPAP management) in children aged 1 to <12 and adolescents aged 12 to <18 years with a high probability for symptomatic, moderate to severe OSA, living in regional, rural or remote areas?	

Abbreviations: AHI=apnoea / hypopnoea index; BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure; ECG=electrocardiogram; EEG=electroencephalogram; EMG=electromyogram; ENT=ear, nose and throat; EOG=electrooculogram; MBS=Medicare Benefits Schedule; OSA=obstructive sleep apnoea; SDB=sleep disordered breathing; PSG=polysomnography.

[a] Item 1 of proposed new MBS item numbers is for children.

[b] Item 2 of proposed new MBS item numbers is for adolescents; adolescents may be referred to paediatric or adult sleep medicine practitioners.

PICO criteria

Population

Table 22 Summary of proposed paediatric populations for Level 4 pulse oximetry study (scenario after items listed)

Study Type	Target Paediatric Population
Diagnostic	
Level 4	Children/adolescents 1 to <18 years living in regional, rural or remote areas (i.e., MM2-7) who are unable to access an accredited sleep laboratory.

Level 4 pulse oximetry studies are not used in infants due to a higher prevalence of central sleep apnoea in children under 1 years old. Therefore it is difficult to differentiate whether desaturations detected on oximetry are due to OSA or central sleep apnoea. Level 4 pulse oximetry studies, however, only involve a single probe and the attached lead is attached to the child's finger or toe, which makes pulse oximetry manageable in an out-of-laboratory setting for children as young as 1 year old. In addition, the applicant has cited evidence of use of pulse oximetry in children aged 1 to 12 years old.

Population – PICO Set 4

The target population for Level 4 pulse oximetry studies is paediatric patients (children aged 1 to ≤12 and adolescents 12 to <18 years) with suspected moderate to severe OSA who live in regional, rural or remote areas. Note that this population may be different to those who have been referred directly to ENT surgeons from primary care. As depicted in Figure 2, patients who are directly referred to ENT surgeons by their general practitioner (GP) are likely to have a different clinical picture in comparison to patients who are referred to sleep physicians and triaged for a Level 4 pulse oximetry study (the target population for PICO Set 4).

The purpose of the overnight pulse oximetry is to triage referrals, made by sleep practitioners for ENT surgery in patients from regional/remote areas. The study will inform decision-making about who requires urgent surgery and will enable referral of those children diagnosed with OSA for surgical review and treatment.

The results of the Level 4 pulse oximetry study will also inform the most appropriate location for surgery for management of patient safety – children with seriously severely obstructed breathing tend to recover poorly and more frequently require post-operative emergency transfers and/or intubation. Therefore, it would be safer if their surgery takes place at a centre that can provide higher level care (a patient requiring emergency breathing support or intubation would usually be admitted to an intensive care unit [ICU]). This is consistent with the applicant's guidance (Pavone et al., 2017).

An overnight pulse oximetry study can only diagnose OSA if the result (McGill score) is positive. Unlike Level 1 PSG, overnight pulse oximetry can only reliably 'rule in' (approximately 30% of cases) but can not 'rule-out' OSA (see discussion in Level 4 Studies (PICO Set 4) p51 . A failed study where the child (or adolescent) has failed to sleep for the minimum six hours, or equipment was set up incorrectly, can be repeated. Otherwise, patients with negative results from a Level 4 pulse oximetry study (up to 70% of cases) will require further investigation. These patients will need to be referred for a Level 2 or Level 1 PSG study.

The application estimated that 20% of the 9,390 currently on the waiting list live in regional, rural or remote areas (Table 7).

In the application, regional and remote areas were defined as >50 km from a paediatric sleep medicine service; however, the Department has advised that MBS items cannot be restricted based on distance from a facility. Other MBS items use the Modified Monash (MM) model of remoteness in descriptors as these can apply to either MBS prescribers or MBS service providers.

The MM model has assigned every address in Australia to 7 locations[1], MM1 – MM7 as follows:

- MM1 covers capital city metropolitan areas (not including Hobart or Darwin)
- MM2 covers regional centres and outer suburbs of capital cities (also metropolitan Hobart and Darwin)
- MM3 – MM5 represents large, medium and small rural towns, respectively
- MM6 – MM7 are remote and very remote communities.

Further discussion of MM locations as a proxy for rural and remote patients is in Proposed descriptor text, p56.

The application stated that at present, patients in this population are either not being diagnosed with OSA (due to long wait lists for a Level 1 PSG study), or are being referred directly for consideration of ENT surgery, if OSA is considered present on clinical grounds. However, MBS claims data shows that this may not strictly be the case (see **Appendix A** – Paediatric sleep study MBS claims data).

At the August 2022 PASC meeting, PASC questioned whether the listing of out-of-laboratory sleep studies may lead to increased referrals for sleep studies that are not clinically necessary to confirm a diagnosis and inappropriately delay patients who are most likely to benefit from being directly referred for surgery. For example, PASC (August 2022) noted that some patients presenting with enlarged adenoids and tonsils can be diagnosed clinically and referred directly for adenotonsillectomy with resolution of OSA in 80-90% and that a very small number require a sleep study for a failed operation. PASC (August 2022) was uncertain whether this issue could be addressed by defining the eligibility criteria for the out-of-laboratory sleep studies more carefully but considered that further consideration and clarification of this is required to prevent unnecessary excess testing with sleep studies. Subsequently, the applicant advised (28 October 2022 pre-PASC videoconference), that a number of suspected OSA patients are being referred directly to ENT by GPs and paediatricians – the figure for resolution of OSA by adenotonsillectomy most likely draws heavily on these patients. In comparison, patients being referred for ENT by sleep physicians on the basis of Level 4 pulse oximetry studies will be a somewhat different group of patients judged to require a sleep study of some kind ahead of surgery.

The applicant noted that Level 4 pulse oximetry studies are not suitable for patients with sensory or behavioural issues and intolerance to head leads (the proposed Level 3 cardiorespiratory patient population) because pulse oximetry cannot distinguish between central and obstructive sleep apnoea, and central disease is more common in the proposed population for Level 3 cardiorespiratory studies.

PASC noted the proposed population for Level 4 studies are children with SDB who live in regional or remote areas, to confirm diagnosis of OSA and to identify patients at high post-operative risk following ENT surgery and therefore triage these children to undergo ENT surgery in a hospital with paediatric ICU facilities. PASC noted the Department questioned, on the basis that Level 4 studies can be used to predict surgical risk (i.e. prognostic test) for regional/remote patients, whether Level 4 sleep studies should also be available to assess surgical risk in paediatric and adolescent patients in metropolitan areas. These patients may also

[1] https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator/health-workforce-locator

have difficulty accessing paediatric ICU facilities and would benefit from an accessible prognostic test, such as a Level 4 study, to help direct the location of surgery. The applicant explained that their first priority was to improve access for children in regional, rural and remote areas, acknowledging that children living in closer proximity to tertiary hospitals have better access to sleep study services. However, PASC considered that this issue remains unresolved and requires further discussion with the applicant out of session before the PICO can be ratified.

Table 23 Summary of utilisation assumptions and estimates for Level 4 pulse oximetry

PICO Set	Age	Study Type	Level 1 PSG wait-list estimate	Assumption / Proportion (based on Applicant review of wait listed patients)	Estimated Number of Patients
Diagnostic					
PICO Set 4	1 to <12 yr	Level 4	7,748	∞20% of patients likely to live in rural, regional or remote areas	1,550
PICO Set 4	12 to <18 yr	Level 4	1,621		324

∞The applicant's 20% estimate (of current wait-list) for Level 4 pulse oximetry studies is consistent with MBS data supplied by the Department: Of the 6,566 claims for paediatric sleep studies in the 2021/2022 financial year, 1276 patients (19.4%) are from MM2 – MM7.

PASC also noted that approximately 20% of patients currently on the waiting list are outside Modified Monash area 1, so an MBS item for Level 4 sleep studies (PICO 4) may also have limited impact on the waiting list. The applicant explained that the waiting lists were continuing to increase and the proposed items would result in a considerable decrease in caseload backlog.

Intervention

Proposed Item

The proposed item is level 4 pulse oximetry study (PICO Set 4) for triage / diagnosis.

Age groups and other information for Level 4 pulse oximetry items is summarised in Table 26 (a version of this table also including proposed fees and maximum frequency is presented elsewhere in Table 33).

Table 24 Proposed MBS sleep study items (incorporating PASC [August 2022] feedback)

#	Age	Study Type	Purpose
Diagnostic			
5	1 ≤12 yr	Level 4	Investigation / diagnosis of suspected OSA in children who live in a regional, rural or remote location and unable to access an accredited sleep laboratory (i.e. referred by a medical practitioner in MM2-7)
6	12 ≤18 yr	Level 4	Investigation / diagnosis of suspected OSA in adolescents who live in a regional, rural or remote location and unable to access an accredited sleep laboratory (i.e. referred by a medical practitioner in MM2-7)

Abbreviations: MM=Modified Monash category of geographical remoteness (MM1-MM7); OSA=obstructive sleep apnoea; yr=year.

The description for Level 4 pulse oximetry studies is summarised in Table 27.

Table 25 Summary description of Level 4 pulse oximetry study

Sleep study	Description
Level 4	• Limited channel pulse oximetry study performed out-of-laboratory, at patient's home or similar • Pulse oximetry equipment shipped to patient ahead of study • No in-person sleep laboratory staff present at patient's home • Trained sleep technician available throughout the study at the sleep laboratory via telephone or other means • Parent/guardian in attendance • Measures two to four parameters, e.g., SpO2 and pulse. Potentially also airflow and TcCO2 • Not currently listed on the MBS • 8 hours' duration

Source : Adapted from Table 1 of report for MSAC 1130 application and Pamula et al., 2017.
Abbreviations: MBS=Medicare Benefits Schedule; SpO_2=peripheral oxygen saturation; $TcCO_2$=transcutaneous carbon dioxide.

Level 4 pulse oximetry studies are not 'PSG' studies, and are sometimes described as 'abbreviated testing' or 'limited channel studies'. Level 4 pulse oximetry measures heart rate and peripheral oxygen saturation (SpO_2). This can be diagnostic of OSA if results are positive. Otherwise, further investigation is required if results are negative.

Level 4 Pulse Oximetry Studies (PICO Set 4)

The Level 4 pulse oximetry is a screening tool with a diagnostic component that is proposed for use in a population that otherwise would have no access to sleep studies, in- or out-of-laboratory settings.

The ASA's Guideline on Pulse Oximetry (Twiss et al., 2019) studies states that: "Pre-operative oximetry has been validated as a tool to help predict respiratory compromise post-operative risk (airway compromise) in children having adenotonsillectomy for OSA".

Risk is calculated as a McGill Oximetry Score, with an increasing score corresponding to increasing risk of post-operative complications. For patients with the highest risk (McGill scores of 3 or 4), the ASA's guideline recommends the following:

- Overnight admission in a facility with after-hours expertise in paediatric airway management*.
- Appropriate caution with opiate administration.
- Continuous oximetry monitoring (including in the post-anaesthetic care unit).

[*Typically such a facility would be a paediatric intensive care unit.]

The use of pulse oximetry in this setting (i.e. predict post-operative risk) is as a prognostic test. The prognostic capability of Level 4 pulse oximetry studies will also need to be assessed during the evaluation stage. Therefore, surgical risk as a prognostic outcome has been included in PICO Set 4 accordingly.

This type of sleep study provides a score based on desaturation events and other, smaller drops in SpO_2. However, OSA (including quite serious OSA), can be present in the absence of these events. The ASA guideline states that a positive McGill Oximetry Score has a 98% positive predictive value for the presence of OSA, but the method only has a sensitivity of 43%. This is why this method can be used to confidently rule in OSA in case of a positive result (desaturations detected) but cannot rule out OSA if the result is negative. The poor sensitivity also accounts for the relatively large number of inconclusive studies (negative result, study itself and data recorded was adequate). Due to the low sensitivity of this methodology, it is unlikely that this type of sleep study would be used in patient groups where Level 1 or Level 2 PSG studies are accessible. Level 4 pulse oximetry studies require a pulse oximeter with a single probe / lead to be attached to the patient to measure two parameters:

i) heart rate / pulse
ii) saturation (SpO_2).

Most currently available pulse oximeters only measure these two parameters. The applicant advised (pre-PASC video conference 28 October 2022) that, as a result, Level 4 pulse oximetry studies typically do not measure $TcCO_2$. Such devices are, however, in development and once a device becomes more widely available that does measure all three parameters using a single probe (pulse, SpO_2 and $TcCO_2$), these would most likely be used in Level 4 pulse oximetry studies.

In the applicant's pre-PASC response for the August 2022 meeting, the applicant noted that 9% of positive tests detected by home pulse oximetry were suggestive of high risk of post-operative complications after adenotonsillectomy (Pavone et al., 2017). This may have implications for service utilisation, noting each city in Australia only has 1-2 centres with a paediatric intensive care unit.

At the August 2022 PASC meeting, PASC raised a suite of issues regarding the proposed Level 4 pulse oximetry studies, which for brevity are reproduced in the Appendix B - PASC comments from August 2022 meeting.

The rationale behind Level 4 pulse oximetry studies is that the patient's local GP (or their paediatrician) would refer them to one of the paediatric sleep clinics (by definition, these are in the major cities only). The patient would be seen by the sleep physician in order for the sleep physician to order the Level 4 pulse oximetry study. It is assumed that this first consultation would be a telehealth item for essentially all patients who then go on to have a Level 4 pulse oximetry study (and receive the pulse oximeter equipment by courier or equivalent). The applicant confirmed this reflects current practice and is achievable.

The need for a trained sleep technician for the Level 2 PSG and Level 3 cardiorespiratory studies limits the availability of those items to patients in remote locations or at a distance from the nearest paediatric sleep laboratory. Listing of Level 4 pulse oximetry studies aims to address that inequity of access.

Claimed benefits

The claimed benefits of listing Level 4 pulse oximetry studies put forward by the applicant are summarised in Table 28.

Table 26 Claimed benefits of paediatric sleep study item listing

Study Type	Claimed Benefits
Level 4 pulse oximetry studies	• Rapid triage of a proportion of referrals for children with suspected moderate to severe OSA who live in regional, rural or remote areas with limited / no access to an accredited paediatric sleep laboratory • More timely and safer ENT surgery for those at risk of surgical complications by directing them to higher level care centres; reduction in unplanned post-operative emergency transfers and / or intubation.

Abbreviations: ENT=ear, nose & throat; OSA=obstructive sleep apnoea

Summary of performance

Table 27 Summary of available sleep study performance characteristics

Study Type	False Positives	False Negatives	Rates of failed or inconclusive studies
Level 4	Negligible	[If +ve score: 98% PPV [a] But only 43% sensitivity]	[b] 70% no McGill score available or McGill score 0 – 1 (these patients would be referred for a Level 1 or 2 PSG study)

Source: Table compiled for this PICO Confirmation.
Abbreviations: PPV=positive predictive value.
[a] 43% sensitivity value is from the ASA Guideline for paediatric pulse oximetry studies (Twiss et al., 2016).
[b] the 70% value for failed or inconclusive studies (Level 4) were supplied by the applicant.

The applicant clarified that the 70% failed or inconclusive study rate for Level 4 pulse oximetry studies was sourced from Nixon et al., (2004)[2].

PASC reiterated concerns about the feasibility of being able to demonstrate comparative effectiveness (and subsequently cost-effectiveness) of Level 4 sleep studies, particularly against Level 1 studies given that Level 4 studies have a high rate of inconclusive results (70%). The applicant responded that inconclusive tests do not reflect test failures but indicates that OSA may be present without abnormal oximetry. The applicant claimed that an inconclusive test can therefore provide information for the sleep specialist in terms of ongoing care and management of the child, including whether they could be managed medically with review, or safely referred to an ENT surgeon for treatment at a regional centre.

PASC discussed the likely extent that further testing would be carried out for patients with a normal or inconclusive result from a Level 4 study. The applicant anticipates that a subset of patients would require further (Level 1 or 2) testing if questions remained about their suitability for surgery or, for example, if a parent is reluctant to go ahead with surgery without a clear diagnosis.

PASC noted the claims that children with a McGill score result of 3 or 4 (consistent with more severe sleep apnoea) following a Level 4 study are at higher risk of post-surgery respiratory compromise and should be triaged to a centre that can provide appropriate peri- and post-operative care. PASC noted the concerns raised by the Department that such claims would mean both the diagnostic accuracy and the prognostic ability (i.e. ability to accurately predict post-surgery complications) of Level 4 studies would need to be evaluated, and that such assessment may be challenging due to the limited clinical evidence available.

Comparator(s)

A summary of proposed comparators for Level 4 pulse oximetry is provided in Table 30. A summary of existing MBS sleep study items is provided in Table 4.

Table 28 Comparators for the proposed study type

Study Type	Comparators
Level 4 pulse oximetry studies*	• Main: Level 1 or Level 2 PSG sleep studies • Secondary: o No testing, followed by ENT surgery o No testing, followed by standard non-CPAP management (not including ENT surgery)

Abbreviations: CPAP=continuous positive airway pressure; ENT=ear, nose & throat; MBS=Medicare Benefits Schedule.
* The comparator(s) for Level 4 pulse oximetry studies has not been confirmed by PASC.

The draft PICO considered at the December 2022 PASC meeting presented three potential comparators for the Level 4 pulse oximetry studies in theory. Although in practice, it was not clear to what extent patients fitting the population criteria would actually receive each of these management options (that is, children or adolescents with moderate-to-severe suspected OSA under consideration for ENT surgery in regional/remote locations).

For Level 4 studies (PICO 4), PASC noted that Level 2 sleep studies would not be an appropriate comparator because they are not currently funded in paediatric patients. PASC noted that no testing and standard management may be a more realistic comparator, due to the difficulties this population (rural and remote) has in accessing a Level 1 PSG sleep study. However, PASC also noted that MBS data shows that some regional, rural and remote patients are currently accessing Level 1 sleep studies by travelling to metropolitan centres. Assuming all rural and remote patients are able to undertake this travel, the appropriate comparator from an HTA perspective would be Level 1 studies rather than no sleep study. PASC

[2] Nixon GM, et al. (2004) Planning adenotonsillectomy in children with obstructive sleep apnea: the role of overnight oximetry. *Pediatrics*. 113(1 Pt 1): p. e19-25.

noted that the appropriate comparator for Level 4 studies remains an unresolved issue that will require further discussion and resolution with the applicant out of session (along with other PICO issues for Level 4 studies that remain unresolved).

Outcomes

A summary of proposed outcomes is in Table 31.

Table 29 Summary of proposed outcomes specific to Level 4 studies only

Type	Outcomes
Testing success	Failed test Repeat testing Referrals for Level 1 PSG studies (relevant to all diagnostic items) Referral for Level 2 PSG studies (relevant to Level 3 cardiorespiratory and Level 4 pulse oximetry)
Prognostic outcome (relevant to Level 4 pulse oximetry)	Surgical risk (McGill score) Post-surgical complications (unplanned emergency transfers, intubation)

PASC noted the that use of Level 4 studies as a test to assess a patient's post-operative risk with ENT surgery (to triage high risk children to undergo ENT surgery in a hospital with paediatric ICU facilities) constitutes use as a prognostic test, and therefore required inclusion of prognostic outcomes for Level 4 studies.

Clinical management algorithms

A summary of the changes in clinical management depending on Level 4 pulse oximetry study outcomes, as understood by the evaluator, is in Table 32.

Table 30 Summary of changes in management – diagnosis of OSA

Study Type	Negative result	Positive result	Failed study	Inconclusive result
Level 4	McGill score shows no desaturations. Refer for Level 1 or Level 2 PSG study.	Confirmation of OSA and surgical risk. Triage for ENT surgery according to McGill Score. 9% of Level 4 pulse oximetry results indicate high surgical risk.	Equipment failure or inadequate sleep – repeat study.	As for negative result.

Abbreviations: AHI=apnoea / hypopnea index; CPAP=continuous positive airway pressure; ENT=ear, nose & throat; OSA=obstructive sleep apnoea; SDB=sleep disordered breathing.

However, there were still questions regarding aspects of the clinical algorithms that pertain to Level 4 studies.

PASC noted the Department questioned whether medical practitioners other than sleep physicians (i.e., GPs, paediatricians, or ENT surgeons) should be able to refer patients (living in regional and rural locations) for a Level 4 study to further improve access. PASC noted additional algorithms that depicted medical practitioners other than sleep physicians (i.e., GPs, paediatricians, or ENT surgeons) referring patients for a Level 4 study were provided by the Department. While the applicant had proposed that the sleep studies (including Level 4) should only be referred by a qualified sleep medicine practitioner, PASC noted that it may be challenging for patients to access qualified sleep practitioners in rural and remote areas and this may pose a barrier, even with the availability of telehealth. Therefore, allowing other medical practitioners to refer patients for Level 4 studies may help overcome this barrier. The applicant did not support this and

responded that a qualified paediatric sleep practitioner is inevitably required to interpret the sleep study data, prepare a report and make clinical recommendations; therefore, the referral and fee should remain with the sleep practitioner. PASC heard from the Department that there is a precedent for other specialists to refer patients for Level 4 studies; paediatricians are able to refer patients for a Level 4 study through hospital-in-the-home services of the two major paediatric hospitals in Victoria, and are provided with a report from a sleep practitioner. PASC considered the issue of whether medical practitioners other than sleep physicians should be able to refer patients for Level 4 studies remained unresolved and will require further consideration and discussion with the applicant.

Following the December 2022 PASC meeting, additional input was sought from the applicant in relation the outstanding questions in relation to Level 4 pulse oximetry studies. The applicant advised a separate application for Level 4 pulse oximetry studies will be submitted at a later date after resolving the issues raised by PASC.

Proposal for public funding

Proposed items

A summary of the proposed Level 4 pulse oximetry items for MBS listing, including fees and frequency, is given in Table 33.

Table 31 Proposed MBS sleep study items (including fees and frequency)

#	Age	Study Type	Requested Fee	Adult Fee	Purpose	Maximum Frequency
Diagnostic						
1	1 ≤12 yr	Level 4	$175.85	N/A	Investigation / diagnosis of suspected OSA in a child who lives in a regional, rural or remote location and is unable to access an accredited sleep laboratory (i.e. referred by a medical practitioner in MM2-7)	2 per 12 mo
2	12 ≤18 yr	Level 4	$175.85	N/A	Investigation / diagnosis of suspected OSA in adolescents who live in a regional, rural or remote location and unable to access an accredited sleep laboratory (i.e. referred by a medical practitioner in MM2-7)	2 per 12 mo

Abbreviations: MBS=Medicare Benefits Schedule; MM=Modified Monash category of geographical remoteness (MM1-MM7); mo=month; OSA=obstructive sleep apnoea; yr=year.

At the August 2022 meeting, PASC considered that for the proposed Level 3 cardiorespiratory study, two MBS items were required for the different age groups (children and adolescents) and also separate MBS items were required for diagnostic and monitoring purposes. This is now reflected in items proposed – see Table 17. Similarly, two MBS items for Level 4 pulse oximetry for children and adolescents has now been proposed although the applicant noted there is very limited evidence for level 4 studies in the adolescent age group.

Proposed descriptor text

Table 32 Applicant proposed MBS item descriptor for Level 4 pulse oximetry study

Category 2: Diagnostic Procedures and Investigations
MBS item XXXX Overnight investigation of sleep for at least 8 hours of a patient aged 1 to <12 years to determine the likelihood of a diagnosis of obstructive sleep apnoea, if: a) ~~(i) the patient lives > 50 Km from an accredited paediatric sleep laboratory and has been~~ The patient has been referred by a medical practitioner who provides a service at, or from, a practice location in: a. a Modified Monash 2 area; or b. a Modified Monash 3 area; or c. a Modified Monash 4 area; or d. a Modified Monash 5 area; or e. a Modified Monash 6 area; or f. Modified Monash 7 area; to a qualified paediatric sleep medicine practitioner who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea; and b) ~~(ii)~~ following professional attendance of 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 c) ~~(a)~~ The patient's (aged 1 to <12 yrs) parent/caregiver is phoned by a trained healthcare professional under the supervision of a paediatric sleep medicine specialist and arrangements are made to courier an oximeter to and from their home. Discussions ensure whether phone or video teleconferencing will occur to assist the parent/caregiver in applying the oximeter for an overnight recording [video preference, phone with photos/texting only if IT does not support video]; and d) ~~(b)~~ A trained healthcare professional under the supervision of a paediatric sleep medicine specialist calls [phone or video as previously arranged] on the evening that study is to occur to assist with and ensuring oximeter probe is attached to child correctly for recording. Phone number or data link is given for overnight backup with an accredited paediatric sleep professional or sleep laboratory; and e) ~~(c)~~ Pulse oximetry data is: a. ~~(i)~~ analysed by software to determine oxygen saturation and heart rate profile b. ~~(ii)~~ stored for interpretation and preparation of a report; and f) ~~(d)~~ interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist [who is on staff of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program] with personal direct review of raw data from the original recording of oximeter data from the patient; and g) ~~(e)~~ 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 For each particular patient, up to a maximum of three services across all out of laboratory sleep study types will be applicable in any 12 month period. Applicable only twice in any 12 month period
Fee: $175.85

Source: pp54-55 of 1712 Application Form.docx.
Suggested additions underlined and deletions in strikethrough are presented by the evaluators and the Department.
Abbreviations: ASA = Australasian Sleep Association; NATA = National Association of Testing Authorities

At the August 2022 PASC meeting, PASC (August 2022) noted restricting the Level 4 pulse oximetry study to patients living >50 km from sleep laboratories is not able to be implemented in an MBS item descriptor and the Department had suggested criteria using Modified Monash (MM) 2-7 areas. However, PASC (August 2022) noted that these criteria referred to the practice location of physicians instead of the patient's home. PASC (August 2022) questioned whether the MM areas for the referring physician will be adequate to limit Level 4 pulse oximetry studies to patients who reside in a rural or regional area, given some referral doctors may have more than one provider number e.g., located in a metro and a rural/remote location.

During development of the PICO for the December 2022 PASC meeting, advice from the Department confirmed that using the MM 2-7 areas and restricting based on the referring medical practitioner (e.g. GP, paediatrician, ENT, etc) location is an established implementable way of restricting services to patients in regional, rural and remote locations. The location of the referring medical practitioner was chosen over using the location of the service provided (e.g. sleep physician) as MBS claims data for the 2021-2022 financial year show that providers were located in MM 1, 2 or 3 areas, as such this would not reflect patient location and may incorrectly restrict access.

Proposed frequency

For Level 4 pulse oximetry, the proposal is a maximum of two studies every 12 months.

A maximum of two sleep studies every 12 months per proposed item may be appropriate in most cases, noting the following:

- For PICO Set 4 (Level 4 pulse oximetry study), in most cases it is unlikely that pre-operative overnight pulse oximetry would be needed to be performed more than twice. A second attempt would only be needed in case of a failed study. For most patients a single study would be sufficient.

Next steps

PASC discussed the challenges of progressing the assessment of Level 4 pulse oximetry, given amongst other concerns (i) uncertainty around the appropriate comparator for Level 4 sleep studies, (ii) concerns that the evidence is unlikely to be sufficient to support a claim of non-inferiority to Level 1 studies in terms of diagnostic accuracy or follow through to impacts on patient outcomes and (iii) the evidence is not likely to be sufficient to demonstrate the prognostic ability of Level 4 studies to identify patients at high post-operative risk with ENT surgery to triage patients for ENT surgery.

PASC suggested the applicant should consider whether they wish to proceed with the application including the Level 4 study or whether the Level 4 study should be excluded and dealt with in a separate application. PASC considered that if the applicant decides to progress a separate application for Level 4 pulse oximetry studies then this should progress to ESC and MSAC as a two-stage assessment report (reference the MSAC Process framework, p39).

PASC noted that finalisation of the PICO Confirmation will occur following resolution of the issues raised by PASC and will depend on the applicant's decision regarding progressing the assessment of Level 4 studies, which will be discussed out of session following PASC.

Following the December 2022 PASC meeting, the applicant advised a separate application for Level 4 pulse oximetry studies will be submitted at later date after resolving the issues raised by PASC.