

# Medical Services Advisory Committee (MSAC) Public Summary Document

## *Application No. 1712 – Out-of-laboratory sleep studies in the diagnosis and management of sleep disordered breathing in children & adolescents*

**Applicant:** Australasian Sleep Association

**Date of MSAC consideration:** 4-5 April 2024

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

### **1. Purpose of application**

An application requesting Medicare Benefits Schedule (MBS) listing of out-of-laboratory sleep studies (Levels 2 and 3) for the investigation of sleep disordered breathing (SDB) in children and adolescents (age 3 to <18 years) was received from the Australasian Sleep Association (ASA) by the Department of Health and Aged Care.

### **2. MSAC's advice to the Minister**

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC did not support public funding for out-of-laboratory sleep studies (Level 2 polysomnography (PSG) or Level 3 cardiorespiratory polygraphy (CRP)) for the investigation of sleep disordered breathing (SDB) in children and adolescents (ages 3 to <18 years). MSAC noted that Level 2 PSGs are currently publicly funded under the Medicare Benefits Schedule (MBS) for adult patients aged 18 years or older.

MSAC considered that there was a paucity of evidence for Level 3 CRP sleep studies and noted there was no MBS item for these studies in adults. Based on the available evidence, which was very low certainty, MSAC concluded that the test accuracy of Level 3 CRP (diagnostic) and Level 3 (monitoring) was likely inferior to Level 1 PSG, and failure rates were likely higher. There was no evidence presented to support the claim of superiority for the clinical utility of Level 3 CRP (diagnostic) based on avoidance of tonsillectomy. MSAC considered the incremental diagnostic value of Level 3 CRP (diagnostic) was likely minimal. MSAC noted that the economic evaluations for Level 3 CRP (diagnostic) were also based on sparse data. MSAC noted the population proposed for Level 3 CRP (diagnostic) was difficult to define, which created the potential for unintended use outside of the proposed population. In addition, MSAC considered there was potential for Level 3 CRP (monitoring) to be undertaken in patients who may be eligible for the MBS item but where monitoring is not clinically warranted.

MSAC acknowledged there was a potential clinical need for Level 2 PSG (diagnostic) to increase testing capacity and thereby reduce long wait times for Level 1 PSG. However, MSAC considered that this potential benefit may not be realised given the requirement for a patient to first be referred to a paediatric sleep physician before an out-of-laboratory sleep study can be requested. The likely increased referrals to paediatric sleep physicians coupled with the relatively low number of paediatric sleep physicians may inadvertently create a new access barrier. MSAC considered that, when compared with Level 1 PSG (diagnostic), the evidence suggested that

Level 2 PSG (diagnostic) was non-inferior in test accuracy, effectiveness and safety, although likely inferior in testing success, but MSAC acknowledged that this may be offset by the convenience and accessibility of home-based testing. MSAC considered the certainty of this evidence was low and based on small sample sizes but also acknowledged that it was unlikely that studies with larger sample sizes would be available for a paediatric population.

MSAC noted that the economic evaluation found that Level 2 PSG (diagnostic) was lower cost relative to Level 1 PSG, which was an acceptable result if the conclusion (based on low-certainty evidence) that Level 2 PSG has non-inferior test accuracy compared to Level 1 PSG is correct. MSAC noted that the financial impact of funding Level 2 PSG (diagnostic) was likely to be cost saving only if the growth in utilisation of Level 1 PSG was at least as high as the growth in utilisation of Level 2 PSG (diagnostic).

### **Consumer summary**

This is an application from the Australasian Sleep Association for listing out-of-laboratory sleep studies (Levels 2 and 3) for investigation of sleep disordered breathing (SDB) in children and adolescents (aged 3 to <18 years) on the Medicare Benefits Schedule (MBS).

Many children and adolescents with SDB have obstructive sleep apnoea (OSA), which can be diagnosed with a sleep study. The best type of sleep study (called the gold standard) is a Level 1 sleep study which continuously records multiple parameters (8-13) such as breathing (airflow and respiratory effort), oxygen saturation, carbon dioxide, heart rate and activity plus electrical activity of the brain. These are done as an overnight stay in a hospital or sleep clinic where a sleep technician or sleep nurse is continuously in attendance. However, there are long waiting lists for Level 1 sleep studies, and not all patients can stay overnight for different reasons, or they may live too far away from a sleep study laboratory.

Out-of-laboratory sleep studies are studies that can be done at home or at a local centre. These studies record less parameters than a Level 1 sleep study. A Level 2 sleep study is most similar to a Level 1 sleep study and records a minimum of 7 parameters including breathing (airflow and respiratory movement), oxygen saturation, heart rate and activity, and electrical activity of the brain. A Level 3 sleep study records a minimum of 4 parameters such as heart rate/activity, oxygen saturation and airflow but does not record electrical activity of the brain.

This application proposes MBS funding for Level 2 and Level 3 sleep studies. A parent or carer would need to set the equipment up at home and place sensing electrodes on the child at night before bedtime. There is also an option for some patients to visit a local centre where staff would place the sensing electrodes and the patient would stay there overnight or return home to do the Level 2 or 3 sleep study.

This application was for three different populations. One population was children and adolescents with an otherwise uncomplicated medical history who needed a sleep study to confirm suspected OSA. It was proposed that these patients could access an out-of-laboratory Level 2 sleep study. For the other two populations (children and adolescents intolerant of Level 1 or 2 sleep studies who needed a sleep study to confirm suspected OSA and children and adolescents who have treated OSA and need monitoring) it was proposed that they would be able to access an out-of-laboratory Level 3 sleep study.

MSAC did not support listing out-of-laboratory Level 2 sleep studies for the proposed population. MSAC acknowledged that there are currently long waiting times to access Level 1 sleep studies, but it was unclear from the application how a home-based Level 2 study would help decrease waiting times. This is because the application stated that a paediatric sleep physician would need to refer a patient to the Level 2 study, but there appears to be a shortage of these clinicians, meaning patients would still have to wait. Further, MSAC was

## Consumer summary

concerned that the application did not consider all costs of the service, which means families could face large out-of-pocket costs. The application also did not consider factors such as barriers to telehealth access, patients with disability, families who had low English proficiency, and Aboriginal and Torres Strait Islander cultural needs. MSAC wanted to see more information about how these factors would be resolved before it could make a recommendation on Level 2 sleep studies.

MSAC did not support listing out-of-laboratory Level 3 sleep studies for either of the proposed populations. MSAC considered that there was no research available to show that Level 3 sleep studies produced accurate results. Level 3 sleep studies did not present good value for money. MSAC considered that the benefits claimed in the application would not be realised, and that listing Level 3 sleep studies may lead to unnecessary sleep studies for monitoring. Also, the populations that are proposed to access these studies are difficult to define, meaning more people may end up using them than intended. MSAC did not support Level 3 sleep studies for similar reasons when it considered its use in the adult population in 2010.

### **MSAC's advice to the Commonwealth Minister for Health and Aged Care**

MSAC did not support listing Level 2 sleep studies. MSAC asked the applicant for clarification on the complete costs of the service and how out-of-pocket costs would be reduced; and how this service would be accessed by, for example, people with disabilities or low English proficiency, families living regionally or remotely, and Aboriginal and Torres Strait Islander families.

MSAC did not support Level 3 sleep studies because it did not consider them to be effective, safe or good value for money.

## **3. Summary of consideration and rationale for MSAC's advice**

MSAC noted that this application from the Australasian Sleep Association (ASA) sought MBS listing of out-of-laboratory sleep studies (Levels 2 and 3) for investigation of SDB in children and adolescents (aged 3 to <18 years).

MSAC recalled that, in 2010, it did not support Level 3 and Level 4 sleep studies for adults, or any out-of-laboratory paediatric sleep studies ([application 1130](#)), because there was a lack of comparative evidence and sparse linked evidence to indicate the effectiveness of out-of-laboratory sleep studies for a paediatric population compared to Level 1 sleep studies.

MSAC noted the most common form of SDB is obstructive sleep apnoea (OSA; prevalence of 1–5%), which disrupts sleep quality and cardiorespiratory physiology. The most common cause of OSA is enlarged tonsils and adenoids, and common treatments include surgery (most commonly adenotonsillectomies), intranasal sprays, dental appliances and weight loss.

MSAC noted that the gold standard to diagnose and quantify SDB is in-laboratory polysomnography (Level 1 PSG) studies. However, Level 1 PSG studies are not readily available due to long waiting lists, are time consuming, often require travel to metropolitan centres, and they should be prioritised for those with highest need, particularly those with underlying medical conditions, those younger than two or three years of age, and those in whom severe OSA is suspected. MSAC noted the applicant's claim that listing will improve access to sleep monitoring services (including for rural patients) and consumer satisfaction, and reduce wait times for Level 1 PSG and time to diagnosis and treatment of SDB.

MSAC noted the three populations and PICO sets:

1. Children aged 3 to <12 years and adolescents aged 12 to <18 years with a high probability for symptomatic moderate to severe OSA (intervention: diagnostic out-of-laboratory Level 2 PSG) – considered low-risk patients. The intention is for a Level 2 PSG to replace a Level 1 PSG.
2. Children aged 3 to <12 years and adolescents aged 12 to <18 years with a high probability for symptomatic moderate to severe OSA (intervention: diagnostic out-of-laboratory Level 3 cardiorespiratory polygraphy [CRP]) – patients that cannot tolerate a Level 1 or 2 PSG. The intent is to offer a Level 3 CRP where the patient would not otherwise receive one.
3. Children aged 3 to <12 years and adolescents aged 12 to <18 years who are stable on continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) respiratory support (intervention: out-of-laboratory Level 3 CRP for treatment monitoring). The intention is for Level 3 CRP to replace a Level 1 PSG.

MSAC noted the proposed MBS item descriptors and fees. MSAC considered that a restriction of three studies in a 12-month period was appropriate as this is consistent with the current MBS paediatric sleep study items. MSAC considered that a requirement for all patients to be referred to a paediatric sleep physician mitigated the risk of use in other unintended populations. However MSAC also noted that this requirement may inadvertently reduce access given the limited number of paediatric sleep physicians. MSAC suggested that alternative models, such as referrals through telehealth may need to be considered in cases where attendance access is an issue.

MSAC considered that it is inappropriate to include costs for telehealth consultations in the proposed MBS items or to charge a separate telehealth consultation item. The fee should be sufficient to include technician time for the application of equipment regardless of whether it is done in person or via telehealth. This is consistent with the principle of a complete medical service. MSAC considered that the proposed tests should be classified as Type C procedures as they are out-of-hospital procedures.

MSAC noted the clinical management algorithm for diagnostic sleep studies. MSAC noted the emphasis from the consultation feedback and the clinical claim around improving access to sleep studies; however, MSAC did not receive any feedback that addressed what the unmet clinical need for out of laboratory diagnostic sleep studies is. MSAC considered that the clinical need may be to:

- decrease the number of inappropriate adenotonsillectomies being performed. However, MSAC considered it unclear how the results of a sleep study inform decision making. The decision to perform surgery is a clinical one based on several factors including history of recurrent infections, the age of the patient, comorbidities and patient/family preference. The claim that out-of-laboratory sleep studies would decrease the number of adenotonsillectomies being performed is not supported by evidence. MSAC advised that further evidence was needed to determine whether the parents or carers of symptomatic patients or those with higher surgical risk with normal or mild sleep study results would choose watchful waiting instead of surgery due to their sleep study results.
- decrease wait times for those most in need. However, MSAC considered it unclear what the drivers are for wait times for Level 1 studies. MSAC recommended further evidence was needed to determine whether long waiting lists for Level 1 studies is due to high volumes of low-acuity patients accessing services or whether there is an unmet need for more services to accommodate the needs of high-risk patients.

MSAC noted that ESC had requested further clarification on these issues but this had not been sufficiently addressed by the applicant in its pre-MSAC response.

MSAC noted that, based on the findings in the Australian Atlas of Healthcare Variation, the decision to undertake some adenotonsillectomy surgeries in Australia may not be supported by evidence. MSAC agreed with the ESC recommendation to refer a review of MBS item 41789 to the MBS Review Advisory Committee.

MSAC considered Population 3, children and adolescents receiving respiratory support who are eligible for Level 3 CRP for treatment monitoring. MSAC queried whether routine monitoring using Level 1 PSG was required for clinically stable patients, and whether increasing access to routine monitoring via MBS funded Level 3 CRP could introduce the potential for overservicing.

MSAC noted that consultation feedback from three professional organisations and one consumer body was largely supportive, citing improved access (especially for regional areas), improved wellbeing for patients and families, and better triaging for surgery. The main disadvantages raised were associated with remote monitoring, such as increased rate of signal loss, elevated risk of negative diagnosis and risk of entanglement in the leads.

Regarding safety, MSAC noted that no comparative studies met the inclusion criteria and reported safety outcomes for any of the proposed sleep studies. One included study, Griffiths et al. (2022) – an Australian single-arm, single-centre, retrospective audit of Level 2 PSG studies (diagnostic) – reported no adverse events during the study period. The ASA clinical practice guidelines<sup>1</sup> for sleep studies in children states that, although safety concerns have not been identified, attention to safety is required for unattended studies. The guidelines emphasise the importance of adequate parental instruction and recommends, where possible, that monitors should be set up by trained staff. MSAC noted that in the ratified PICO, the proposed item descriptors for Level 2 and Level 3 sleep studies required that the equipment be applied by a sleep technician, or if this is not possible, by a clinician but did not provide for parent application of the leads.

MSAC noted that although no safety data were identified for Level 3 CRP (diagnostic or monitoring studies), it was inferred to have a lower risk due to reduced equipment requirements. MSAC considered that, theoretically, there could be a difference in exposure to nosocomial respiratory infections for out-of-laboratory settings compared to in-laboratory settings, but no data was available to support this. MSAC considered that this may have heightened relevance to PICO set 3 due to the high rate of complex co-occurring conditions in individuals receiving respiratory support.

MSAC considered that only PICO set 2 is likely to alter the downstream treatment decisions, based on the diagnostic assessment frameworks. There is a theoretical benefit of the Level 3 CRP (diagnostic) from avoiding inappropriate tonsillectomies and the attendant risk of harms, but this is not supported by evidence.

Regarding clinical effectiveness, MSAC agreed with ESC's conclusions that:

- for PICO set 1, the claim of non-inferior test accuracy was uncertain and testing success was likely inferior. However, this may be offset by the convenience of home-based testing. The overall claim of non-inferior effectiveness was uncertain and assumed that the test would be a replacement for Level 1 studies rather than an additional test.

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<sup>1</sup> Pamula Y et al. (2017). [Australasian Sleep Association clinical practice guidelines for performing sleep studies in children](#), *Sleep Med*, 36(Suppl 1):S23–S42.

- for PICO set 2, there was no evidence on test accuracy, although it is likely inferior to Level 1 studies and superior to no sleep study. Clinical utility, effectiveness and testing success was unknown, so it was highly uncertain that the test could improve patient selection for adenotonsillectomy and lead to safer outcomes.
- for PICO set 3, there is likely inferior accuracy and inferior change in management, but this may be offset by likely increased acceptability of Level 3 CRP to the user population.

MSAC noted that a cost-minimisation analysis was undertaken for PICO set 1. The base case results are presented in terms of cost per accurate diagnosis, accounting for the risk of incorrect diagnosis among the intervention group, and the costs of repeat testing because of failure of an initial test. Level 2 PSG has a lower cost per accurate diagnosis than Level 1 PSG. The intervention was lower cost, albeit lower accuracy, than the comparator, but resulted in cost savings of \$645.29 per accurate diagnosis. However, MSAC noted that this result, while acceptable, was premised on the low certainty evidence that test accuracy was non-inferior.

MSAC noted that a cost-effectiveness analysis was undertaken for PICO set 2. A decision tree was constructed simulating the passage of children and adolescents at significant risk of OSA to either Level 3 CRP (intervention) or to no sleep study (comparator). The transition probabilities were derived from non-randomised studies and, where no published data were available, expert opinion was used. As the outcome of interest for the cost-effectiveness analysis was tonsillectomies avoided, the cost of tonsillectomy was used to set a “willingness-to-pay” threshold for the intervention. MSAC noted that the base-case incremental cost per tonsillectomy avoided of \$1,751.65 was less than the expected cost per tonsillectomy (\$2,721.41), meaning that the intervention was considered by the DCAR to be cost-effective by this measure. However, MSAC considered that the claim of tonsillectomies avoided is not supported by evidence, as it is highly uncertain that sleep study findings would overturn operative management decisions. The other key limitations are the lack of utility data and that most of the clinical inputs were based on non-randomised data or expert opinion. The evaluation is based on very sparse data ( $n = 34$ ). In addition, potential downstream benefits of avoiding tonsillectomies could not be quantified and were excluded. MSAC agreed with ESC that a cost-utility analysis (rather than a cost-effectiveness analysis) is preferred for decision making.

MSAC noted that, due to the limited evidence available for PICO set 3, a costing analysis was undertaken. The proposed fees for the new MBS items (\$284.19) are much lower than existing MBS items for Level 1 PSG (\$768.70 and \$692.50) because of lower clinician staffing costs for out-of-laboratory sleep studies. This was not a comprehensive cost analysis because it only considered MBS fees. The evaluation of the consequences of the out-of-laboratory studies in comparison to Level 1 PSG is limited by a lack of appropriate data.

MSAC noted that a combined epidemiological and market-share approach was taken to estimate the use of paediatric out-of-laboratory sleep studies in Australia and estimate budget impact. For PICO set 1, MSAC noted that the applicant estimated that 30% of wait-listed children and adolescents are likely to be eligible for Level 2 PSG. The net financial impact to the MBS is estimated to be a cost saving of \$461,109 in year 1, rising to an additional cost to the MBS of \$306,739 in year 6 due to the greater growth rate of Level 2 studies compared to Level 1 services. If the growth rate is the same for Level 1 and Level 2 studies, the proposed service remains cost saving. The costs are predominately attributable to use of the items for children rather than adolescents.

For PICO set 2, MSAC noted that the applicant estimated that 5% of wait-listed children and adolescents are likely to be suitable for Level 3 CRP. The net financial impact to the MBS is estimated to be \$134,102 in year 1, rising to \$269,728 in year 6. No Level 1 PSG studies are substituted as the comparator for this population is no sleep study.

For PICO set 3, MSAC noted that the applicant estimated 1,045 children and adolescents required respiratory support in Australia in 2009. Half of these were estimated to be suitable for out-of-laboratory monitoring. The net financial impact to the MBS is a cost saving due to the substitution of Level 3 studies for Level 1 monitoring studies; it is estimated to be a saving of \$364,624 in year 1, rising to a saving of \$465,362 in year 6.

MSAC considered that if half of the recommended monitoring visits are undertaken but the introduction of Level 3 CRP monitoring results in all patients undergoing recommended monitoring, then the substitution rate would be two Level 3 CRPs for every one Level 1 PSG, thereby reducing the cost saving to \$56,096 in year 1 to \$71,594 in year 6.

MSAC noted that the combined budget impact was a net saving of \$691,631 in year 1 and a net cost of \$111,105 in year 6.

MSAC considered the possibility of the use of out-of-laboratory sleep studies outside of the intended populations to be high for all three populations:

- Population 1 – although the eligible population for Level 2 PSG are those with a high probability of OSA, in reality it is possible that it may be used for patients across the full spectrum of SDB (from mild to severe).
- Population 2 – patients who cannot tolerate a Level 1 or 2 PSG may be difficult to define, so there is potential for use outside the intended population.
- Population 3 – it is unclear whether laboratory-based sleep studies were required for patients who are clinically stable and whether monitoring would occur unnecessarily with increased access to out-of-laboratory options.

Based on current data on patient out-of-pocket costs for MBS items 12210 and 12213, MSAC noted that ESC had considered that out-of-pocket costs may be substantial relative to average fees charged. MSAC agreed with ESC that these out-of-pocket costs may be proportionally higher for patients who live further away if the cost of equipment delivery, setup and return of equipment is billed separately to the patient, which could lead to access issues.

MSAC agreed with ESC that there may be additional access issues arising from unintended consequences:

- Sleep laboratory sites may face reduced incentives to maintain current skills in accommodating children with disability or sensory support needs if home-based options become available.
- Potential removal of transport subsidies for remote patients who prefer to have a laboratory sleep study as home-based options become available.

MSAC disagreed with the suggestion that providers should be accredited by the National Association of Testing Authorities, as this is not a requirement for adult MBS items and may worsen access.

Overall, MSAC did not support listing Level 3 CRP studies for populations 2 and 3. MSAC considered that the clinical claim of superiority for clinical utility is not supported by evidence. No studies met inclusion criteria for change in management for population 2. The clinical claim put forward by the applicant that the intervention for PICO set 2 could lead to a reduction in tonsillectomies is largely speculative. There is no evidence available to suggest that a Level 3 CRP sleep study will overturn any previous recommendations for surgery. Many clinical factors, in addition to sleep study results, are considered when a decision is being made to progress to adenotonsillectomy, and these operations may occur even if the sleep study is negative for OSA. In addition, MSAC considered that the evidence supporting Level 3 CRP had a high risk of bias,

and there were issues with diagnostic accuracy and high test failure rates. The incremental diagnostic value is likely to be minimal (or zero) in the study populations. No evidence on incremental value was identified for the target population. MSAC considered that there was uncertainty in the applicability of the evidence to the intended use population (population 2), due to uncertainty whether the study populations were reflective of population 2 (patients unable to tolerate Level 1 or 2 PSG).

MSAC considered that the economic evaluation for PICO set 2 is uncertain because it is based on very sparse data and is limited by the lack of utility data. Most of the clinical inputs are based on non-randomised data or expert opinion. The cost-effectiveness analysis is based on a willingness-to-pay threshold that is set at the cost of performing a tonsillectomy. However, the claim of tonsillectomies avoided is not supported by the evidence for the reasons discussed. Further, MSAC considered that children who cannot tolerate an in-laboratory sleep study (population 2) may be difficult to define, thus there is the potential for leakage. For population 3, it is unclear whether laboratory-based sleep studies are required for patients who are clinically stable, and whether Level 3 CRP for monitoring purposes will occur unnecessarily in clinical practice for clinically stable patients (that is, there is the potential for overservicing) given that Level 3 CRP is a more accessible and easier-to-administer sleep test.

MSAC considered that any resubmission for a Level 3 CRP would need to demonstrate a clear clinical need, and would need higher-level evidence to support, as a minimum, non-inferior clinical effectiveness, safety and cost-effectiveness. MSAC considered that a very clear justification to fund Level 3 studies in the paediatric population would be required given that it is not currently funded in the adult population. The use of the appropriate economic evaluation tool is recommended, noting that a cost-utility analysis is the preferred method for MSAC decision making.

MSAC considered that Level 2 PSG studies have non-inferior test accuracy, non-inferior effectiveness and non-inferior safety compared to Level 1 studies. The use of Level 2 PSG studies resulted in inferior testing success (failure rates of 9–19%), but this may be offset by the convenience of home-based testing. MSAC agreed with ESC that the evidence for these studies is uncertain because of small sample sizes, but it is unlikely that larger studies will be available for a paediatric indication. It is noted that additional sources of supporting evidence were used to address gaps in evidence in this application. MSAC noted that there is no evidence for change in management for population 1, but considered it reasonable to assume that a diagnosis of OSA (or otherwise) will lead to the same treatment decisions regardless of whether the diagnosis was made by a Level 1 or 2 PSG.

MSAC acknowledged that Level 2 PSG are available on the MBS for adults.

MSAC considered that, for a resubmission for Level 2 PSG, the applicant would need to demonstrate:

- a clear clinical need, and provide a clear description of how the service will meet this need. The main clinical need appears to be addressing the long wait times for a Level 1 PSG. The applicant estimates 30% of wait-list patients can be assessed with a Level 2 PSG in place of in-laboratory PSG, however this estimation requires justification.
- how the requirement for a patient to be referred to a paediatric sleep physician will address waiting times, noting the relatively low number and distribution of paediatric sleep physicians. This requirement may inadvertently reduce access as there will likely be increased demand for consultations with paediatric sleep physicians, particularly if additional testing is required which may lead to subsequent consultations occurring in a larger cohort of patients than expected.



- how the entire Level 2 PSG service will be funded, including all sources such as MBS and non-MBS funding. This may require
  - an examination of out-of-pocket costs and how these can be mitigated – for example, if cost of equipment delivery, setup and return of the equipment is borne by the patient, which may result in cost inequities depending on the patient’s geographical location.
  - an examination of equity and access barriers and how these can be overcome, and include any costs associated with this – this may include additional consumer consultation with families in remote locations, patients with disability, families with low English proficiency, and Aboriginal and Torres Strait Islander families.
  - as noted previously, MSAC considered that to be consistent with the principle of a complete medical service, the fee should be sufficient to include technician time for the application of equipment regardless of whether it is done in person or via telehealth. The fee structure should also align with current MBS sleep study items using the adult attended versus unattended fee differential as the guide.

MSAC advised that given that NATA accreditation is not recommended, the resubmission will need to demonstrate a mechanism by which service providers can provide robust oversight to Level 2 PSG testing. It is vital that service providers ensure that parents are properly briefed on how to use the equipment and the supervision that is required for home-based testing or offer an alternative option where the leads can be attached by a trained health professional located in the community e.g. pharmacy. MSAC advised that the intent behind the requirement for a sleep physician should remain so that patients are appropriately allocated to either Level 1 or 2 studies. There should be further evaluation on whether the item descriptor includes this requirement and its impacts on access to paediatric sleep physicians and sleep studies. The economic evaluation and financial impacts will need to be revised to incorporate the above considerations.

## 4. Background

MSAC has previously considered out-of-laboratory sleep studies in the diagnosis and management of obstructive sleep apnoea (OSA) ([MSAC application 1130](#)). MSAC application 1130 considered four clinical pathways for out-of-laboratory (referred to as ‘unattended’) sleep studies in OSA:

1. diagnosis in a non-specialised unit
2. diagnosis in a referral setting
3. diagnosis and reassessment (if symptoms recur despite ongoing treatment) in a paediatric setting
4. reassessment in an adult setting.

MSAC supported Level 2 unattended sleep studies for the investigation of OSA in adults on a referred basis. MSAC did not support public funding for Level 3 or Level 4 unattended sleep studies or for any unattended sleep studies for diagnosis in a paediatric setting or for reassessment of treatment efficacy. MBS item 12250 for unattended (home-based) sleep studies in adults was first listed on 1 October 2008 as an interim listing and was retained following MSAC’s recommendations in 2010 in response to application 1130.

Table 1 lists the matters of concern raised in the [Public Summary Document \(PSD\)](#) by MSAC in relation to the assessment of the paediatric population in MSAC application 1130 and the areas in the current DCAR that address these concerns.

**Table 1 Summary of key matters of concern for MSAC application 1130**

<b>Component</b>	<b>Matter of concern</b>	<b>How the current assessment report addresses it</b>
Clinical effectiveness	MSAC acknowledged there was a lack of comparative evidence and sparse linked evidence to indicate the effectiveness of unattended sleep studies for a paediatric population, relative to Level 1 sleep studies (PSD, p.4).	MSAC application 1130 included no studies of Level 2 PSG and two diagnostic accuracy studies of Level 3 CRP (Jacob et al. 1995; Zucconi et al. 2003). Neither of the Level 3 studies met inclusion criteria for the current DCAR.  The evidence remains sparse, however diagnostic accuracy studies were identified for both Level 2 PSG and Level 3 CRP. The studies are small and this is unlikely to change for a paediatric indication. Additional sources of supporting evidence were used to address gaps in evidence.

MSAC = Medical Services Advisory Committee; PSD = Public Summary Document.

MSAC has previously considered a home sleep apnoea test that used peripheral arterial tone for the diagnosis of OSA in adult patients (WatchPAT, MSAC application 1631, considered 29-30 July 2021). The intervention in application 1631 was not within scope of the current DCAR because the absence of airflow measurement makes the WatchPAT device inappropriate for Level 3 cardiorespiratory studies under the definition of the current assessment.

## **5. Prerequisites to implementation of any funding advice**

The proposed services are performed using sleep monitoring devices that have been validated for use in paediatrics. Several medical devices that are used in out-of-laboratory sleep studies are currently included on the Australian Register of Therapeutic Goods (ARTG).

The applicant proposed that only National Association of Testing Authorities (NATA) accredited paediatric sleep laboratories should be eligible as service providers in order to manage quality requirements specific to paediatric studies. It is not known how many paediatric sleep laboratories are currently operating without NATA accreditation. At least one public hospital sleep laboratory (Canberra Hospital) is not NATA accredited. It is not known if this example is an exception to the norm. If it is not, a requirement for accreditation of providers may inadvertently restrict access to subsidised care.

## **6. Proposal for public funding**

Currently, diagnosis of SDB in children and adolescents is undertaken by polysomnography (PSG) in a sleep laboratory (Level 1 PSG) and this service is MBS listed. The proposed medical services are out-of-laboratory sleep studies, usually in the patients' homes (Level 2 PSG or Level 3 cardiorespiratory polygraphy (CRP)). The provision of out-of-laboratory sleep studies were claimed by the applicant to offer improved access to sleep monitoring services, improved consumer satisfaction, reduced wait times for Level 1 PSG and reduced time to diagnosis and treatment of SDB.

The proposed items for MBS listing, including fees and frequency, are summarised in Table 2.

**Table 2 Summary of proposed MBS out-of-laboratory sleep study items**

Age (years)	Study Type	Proposed Fee <sup>a</sup>	Purpose	Max. frequency (in 12 months) <sup>d</sup>
3 to < 12 <sup>b</sup>	Level 2	\$415.65	Investigation of suspected OSA in children	3 of any out-of-laboratory sleep studies
12 to < 18 <sup>c</sup>	Level 2	\$364.32	Investigation of suspected OSA in adolescents	3 of any out-of-laboratory sleep studies
3 to < 12 <sup>b</sup>	Level 3	\$284.19	Investigation of suspected OSA in children unlikely to tolerate head leads	3 of any out-of-laboratory sleep studies
12 to < 18 <sup>c</sup>	Level 3	\$284.19	Investigation of suspected OSA in adolescents unlikely to tolerate head leads	3 of any out-of-laboratory sleep studies
3 to < 12 <sup>b</sup>	Level 3	\$284.19	Follow-up (monitoring) in a child with diagnosed OSA	3 of any out-of-laboratory sleep studies
12 to < 18 <sup>c</sup>	Level 3	\$284.19	Follow-up (monitoring) in an adolescent with diagnosed OSA	3 of any out-of-laboratory sleep studies

ASA = Australasian Sleep Association; Max = maximum; MBS = Medicare Benefits Schedule; NATA = National Association of Testing Authorities; OSA = obstructive sleep apnoea; RACP = Royal Australasian College of Physicians.

<sup>a</sup> The proposed fees have been revised from those presented in the PICO confirmation. The travel costs originally included by the applicant have been removed.

<sup>b</sup> Items for children (3 to <12 y) are for ordering by clinicians qualified in paediatric sleep medicine by the RACP and listed as a clinician with a paediatric sleep laboratory accredited with the ASA/NATA Sleep Disorders Service Accreditation Program.

<sup>c</sup> Adolescent items (age 12 to < 18 y) are for ordering by clinicians qualified in adult or paediatric sleep medicine by RACP and listed as a clinician on staff with an adult or paediatric sleep laboratory accredited under the ASA/NATA Sleep Disorders Service Accreditation Program.

<sup>d</sup> The frequency proposed in this assessment is a maximum of three of any of the proposed paediatric out-of-laboratory sleep study items.

Separate MBS items are proposed for children and adolescents as recommended by PASC. All items for children aged 12 and under require referral to a paediatric sleep medicine practitioner. The paediatric sleep medicine practitioner will then order a sleep study for eligible patients suited to an out-of-laboratory setting. Adolescent sleep studies may be ordered by either a paediatric or adult sleep medicine practitioner.

The fees proposed by the applicant have been revised to remove fuel and travel costs, as these costs are business expenses and not within the definition of the professional service provided. It was considered that approximately 38% of paediatric OSA patients were likely to be in rural, regional or remote areas. Furthermore, all these patients were considered likely to require significant telehealth involvement as part of the proposed sleep study items, especially if parents needed remote instruction for setting up the sleep study equipment. The applicant has included costing for half an hour of telehealth as part of the proposed fee, but this may not be adequate for patients in these areas requiring remote instruction (see Section 5.4 Telehealth assistance for at home sleep studies).

The applicant has requested all items to have a frequency restriction of twice in any 12-month period. Based on data provided by the Department, individual paediatric patients typically use a maximum of three sleep study services in a 12-month period (although the number of visits may reflect restricted access to paediatric sleep study facilities). Hence, it is proposed that the frequency criterion be a maximum of any three out-of-laboratory sleep study items in a 12-month period.

The applicant requested a distance criterion whereby patients living greater than 50 km from a sleep laboratory could have their parent or caregiver apply the sleep study equipment under telehealth instruction from a qualified sleep laboratory staff member (patients living closer would not have this option). PASC acknowledged that a distance criterion could not be incorporated in an MBS item and as such it has been removed. Instead, the possibility for the equipment to be

applied either by a qualified sleep laboratory staff member or by a parent under instruction have been presented as alternatives with no restriction on the distance of the patient's residence from a sleep laboratory. While a distance criterion provides a rule of thumb for service providers, it was considered unlikely that the item required wording to limit who may apply the equipment if the providers will be subject to NATA accreditation (whereby the sleep laboratory quality systems would manage these issues, and be subject to audit).

For patients requiring a parent to set up the equipment under remote instruction, telehealth assistance is likely to be a key component to ensure a successful sleep study can be obtained. The proposed fees may need to be adjusted to incorporate a larger telehealth cost component for rural, regional or remote patients, who (as noted above) are likely to comprise around 38% of the target population.

The applicant requested that the proposed sleep study services should be restricted to providers with NATA accreditation along similar lines to current accreditation requirements for pathology and diagnostic imaging services on the MBS.

The proposed item descriptors in Table 3, Table 4 and Table 5 have been adapted from the existing MBS items for paediatric Level 1 PSG (in-laboratory sleep studies). Suggested amendments to the proposed item descriptors are indicated. In particular, the clinical criterion "symptomatic, moderate-to-severe" has been removed as it is limited to the use of the questionnaires for referral of adults for out-of-laboratory studies (MBS item 12250). If this criterion is replaced or revised, it should be considered that clinical assessment alone may not provide a good measure of OSA severity in children. Ordering of a sleep study will still require assessment by a specialist sleep physician (unlike for MBS item 12250 where patients may be referred directly from primary care).

**Table 3 Proposed item descriptors for paediatric Level 2 PSG studies (PICO Set 1)**

<b>Category 2: Diagnostic Procedures and Investigations</b> <b>Group D1. Miscellaneous Diagnostic Procedures And Investigation</b> <b>Subgroup 10. Other Diagnostic Procedures And Investigations</b>	
<p><b>MBS item XXXXX-1</b></p> <p>Overnight investigation of sleep for at least 8 hours, for a patient aged at least 3 years but less than 12 years to confirm diagnosis of obstructive sleep apnoea, if:</p> <p>(a) (i) the patient has been referred by a <del>general</del> <b>medical</b> practitioner to a qualified paediatric sleep medicine practitioner, <del>who</del> <b>after the medical practitioner</b> has determined that the patient has a high probability of <del>symptomatic, moderate to severe</del> obstructive sleep apnoea; and</p> <p>(ii) following professional attendance <b>of on</b> 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</p> <p>(b) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, <b>of</b> a minimum of 7 channels that include (i) to (vii) of the following measures:</p> <p>(i) airflow;</p> <p>(ii) <del>continuous</del> EEG;</p> <p>(iii) <del>continuous</del> EMG;</p> <p>(iv) EOG;</p> <p>(v) <del>continuous</del> ECG <b>or heart rate</b>;</p> <p>(vi) oxygen saturation;</p> <p>(vii) respiratory effort;</p> <p>(viii) (optional) measurement of carbon dioxide (either end tidal or transcutaneous);</p> <p>(c) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner who is on the staff list of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program; and</p> <p>(d) either:</p> <p>(i) the equipment is applied to the patient by a sleep technician; or</p> <p>(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 <del>health professional</del> <b>parent or caregiver</b> is given instructions on how to apply the equipment by an <del>affiliated</del> accredited sleep laboratory.</p> <p>(e) written instructions are given to parent/caregiver to monitor the <del>child</del> <b>patient</b> overnight and a phone contact or data link to the accredited paediatric sleep laboratory to enable trouble shooting overnight if required; and</p> <p>(f) polygraphic records are:</p> <p>(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</p> <p>(ii) stored for interpretation and preparation of a report; and</p> <p>(g) 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</p> <p>(h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203</p> <p>Up to a maximum of 3 sleep study items per patient in any 12-month period from this item and items XXXXX-2, XXXXX-3, XXXXX-4, XXXXX-5 and XXXXX-6.</p> <p>(See para DN.1.17 of explanatory notes to this Category)</p>	<p><b>Fee: \$415.65      Benefit: 75% = \$311.74      85% = \$353.30</b></p>

**MBS item XXXXX-2**

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

- (a) (i) the patient has been referred by a ~~general~~ medical practitioner to a qualified paediatric or adult sleep medicine practitioner, ~~who~~ after the medical practitioner 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 that an out-of-laboratory setting is appropriate for the sleep study; and

(b) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 7 channels that include (i) to (vii) of the following measures:

- (i) airflow;
- (ii) ~~continuous~~-EEG;
- (iii) ~~continuous~~-EMG;
- (iv) EOG;
- (v) ~~continuous~~-ECG or heart rate;
- (vi) oxygen saturation;
- (vii) respiratory effort;
- (viii) (optional) measurement of carbon dioxide (either end tidal or transcutaneous);

(c) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner who is on the staff list of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program; and

(d) either:

- (i) the equipment is applied to the patient by a sleep technician; or
- (ii) if this is not possible – the reason it is not possible for the accredited paediatric or adult sleep laboratory professional to apply the equipment to the patient is documented and a ~~health professional~~ parent or caregiver is given instructions on how to apply the equipment by an ~~affiliated~~-accredited sleep laboratory.

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

(f) polygraphic records are:

- (i) analysed for assessment of sleep stage, arousals, respiratory events, and cardiac abnormalities using manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
- (ii) stored for interpretation and preparation of a report; and

(g) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine specialist 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

(h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Up to a maximum of 3 sleep study items per patient in any 12-month period from this item and items XXXXX-1, XXXXX-3, XXXXX-4, XXXXX-5 and XXXXX-6.

(See para DN.1.17 of explanatory notes to this Category)

**Fee: \$364.32      Benefit: 75% = \$273.23      85% = \$309.67**

ASA = Australasian Sleep Association; CO<sub>2</sub> = carbon dioxide; ECG = electrocardiogram; EEG = electroencephalogram; EMG = electromyogram; EOG = electrooculogram; MBS = Medical Benefits Schedule; NATA = National Association of Testing Authorities  
Suggested additions are underlined in blue text and deletions are in strikethrough.

Source: compiled for this assessment report, adapted from the Ratified PICO confirmation Table 20, Appendix D

**Table 4 Proposed item descriptors for paediatric Level 3 CRP (PICO Set 2)**

<b>Category 2: Diagnostic Procedures and Investigations</b> <b>Group D1. Miscellaneous Diagnostic Procedures And Investigation</b> <b>Subgroup 10. Other Diagnostic Procedures And Investigations</b>		
<b>MBS item XXXXX-3</b>		
Overnight investigation of sleep for at least 8 hours, for a patient aged at least 3 years but less than 12 years to confirm diagnosis of obstructive sleep apnoea, if:		
<p>(a) (i) the patient has been referred by a <del>general</del> <b>medical</b> practitioner to a qualified paediatric sleep medicine practitioner, <del>who</del> <b>after the medical practitioner</b> has determined that the patient has a high probability of <del>symptomatic, moderate to severe obstructive</del> sleep apnoea; and</p> <p><b>(ii) the patient</b> is <del>non-</del><b>intolerant</b> of head leads when full <del>PSG</del> <b>polysomnography is</b> attempted; and</p> <p>(ii) following professional attendance <del>of</del> <b>on</b> 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</p>		
<p>(b) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, <del>of</del> <b>a</b> minimum of 4 channels that include the following measures:</p> <p>(i) airflow;</p> <p>(v) <del>continuous</del> <b>ECG or heart rate</b>;</p> <p>(vi) oxygen saturation;</p> <p>(vii) respiratory effort;</p> <p>(viii) (optional) measurement of carbon dioxide (either end tidal or transcutaneous);</p>		
<p>(c) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner who is on the staff list of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program; and</p>		
<p>(d) either:</p> <p>(i) the equipment is applied to the patient by a sleep technician; or</p> <p>(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 <del>health professional</del> <b>parent or caregiver</b> is given instructions on how to apply the equipment by an <del>affiliated</del> accredited sleep laboratory.</p>		
<p>(e) written instructions are given to parent/caregiver to monitor the <del>child</del> <b>patient</b> overnight and a phone contact or data link to the accredited paediatric sleep laboratory to enable trouble shooting overnight if required; and</p>		
<p>(f) polygraphic records are:</p> <p>(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</p> <p>(ii) stored for interpretation and preparation of a report; and</p>		
<p>(g) 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</p>		
<p>(h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203</p>		
<p>Up to a maximum of 3 sleep study items per patient in any 12-month period from this item and items XXXXX-1, XXXXX-2, XXXXX-4, XXXXX-5 and XXXXX-6.</p>		
<p>(See para DN.1.17 of explanatory notes to this Category)</p>		
<b>Fee: \$284.19</b>	<b>Benefit: 75% = \$213.14</b>	<b>85% = \$241.56</b>

**MBS item XXXXX-4**

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

- (a) (i) the patient has been referred by a ~~general~~ medical practitioner to a qualified paediatric or adult sleep medicine practitioner, ~~who~~ after the medical practitioner has determined that the patient has a high probability of ~~symptomatic, moderate to severe~~ obstructive sleep apnoea; and  
(ii) the patient is ~~non-~~intolerant of head leads when full ~~PSC~~ polysomnography is attempted; and  
(ii) following professional attendance of on the patient (either face to face or by video conference) by a qualified paediatric or adult sleep medicine specialist who determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea and that an out-of-laboratory setting is appropriate for the sleep study; and
- (b) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 4 channels that include the following measures:
- (i) airflow;
  - (v) ~~continuous~~-ECG or heart rate;
  - (vi) oxygen saturation;
  - (vii) respiratory effort;
  - (viii) (optional) measurement of carbon dioxide (either end tidal or transcutaneous);
- (c) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner who is on the staff list of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program; and
- (d) either:
- (i) the equipment is applied to the patient by a sleep technician; or
  - (ii) if this is not possible – the reason it is not possible for the accredited paediatric or adult sleep laboratory professional to apply the equipment to the patient is documented and a ~~health professional~~ parent or caregiver is given instructions on how to apply the equipment by an ~~affiliated~~-accredited sleep laboratory.
- (e) written instructions are given to parent/caregiver to monitor the ~~child~~ patient overnight and a phone contact or data link to the accredited paediatric or adult sleep laboratory to enable trouble shooting overnight if required; and
- (f) polygraphic records are:
- (i) analysed for assessment of sleep stage, arousals, respiratory events, and cardiac abnormalities using manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
  - (ii) stored for interpretation and preparation of a report; and
- (g) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine specialist 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
- (h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Up to a maximum of 3 sleep study items per patient in any 12-month period from this item and items XXXXX-1, XXXXX-2, XXXXX-3, XXXXX-5 and XXXXX-6.

(See para DN.1.17 of explanatory notes to this Category)

**Fee: \$284.19      Benefit: 75% = \$213.14      85% = \$241.56**

ASA = Australasian Sleep Association; CO<sub>2</sub> = carbon dioxide; ECG = electrocardiogram; MBS = Medical Benefits Schedule; NATA = National Association of Testing Authorities

Suggested additions are underlined in blue text and deletions are in strikethrough.

Source: compiled for this assessment report, adapted from the Ratified PICO confirmation Table 21, Appendix E



**Table 5 Proposed item descriptors for Level 3 CRP for patients on non-invasive ventilation (PICO Set 3)**

<b>Category 2: Diagnostic Procedures and Investigations</b> <b>Group D1. Miscellaneous Diagnostic Procedures And Investigation</b> <b>Subgroup 10. Other Diagnostic Procedures And Investigations</b>	
<p><b>MBS item XXXXX-5</b></p> <p>Overnight investigation of sleep for at least 8 hours, for a patient aged at least 3 years but less than 12 years, to <del>confirm</del> <u>assess</u> adequacy of <del>present</del> respiratory support for obstructive sleep apnoea, if:</p> <p>(a) (i) the patient is using Continuous Positive Airway Pressure (CPAP) or other non-invasive ventilation                      (ii) <del>the patient has been referred by a medical practitioner to</del> a qualified paediatric sleep medicine practitioner has determined that the patient is stable on <del>current</del> respiratory support for sleep disordered breathing; and                      (iii) following professional attendance <del>of</del> <u>on</u> 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 <del>therapy (CPAP or bilevel)</del>; and</p> <p>(b) During a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures:</p> <p>(i) airflow;                      (ii) oxygen saturation;                      (iii) respiratory effort;                      (iv) ECG or heart rate                      (v) (optional) measurement of carbon dioxide (either end tidal or transcutaneous);</p> <p>(c) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner who is on the staff list of a paediatric sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program; and</p> <p>(d) either:</p> <p>(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 <del>health professional</del> <u>parent or caregiver</u> is given instructions on how to apply the equipment by an <del>affiliated</del> accredited sleep laboratory.</p> <p>(e) written instructions are given to parent/caregiver to monitor the <del>child</del> <u>patient</u> overnight and a phone contact or data link to the accredited paediatric sleep laboratory to enable trouble shooting overnight if required; and</p> <p>(f) polygraphic records are:</p> <p>(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</p> <p>(g) 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</p> <p>(h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203</p> <p>Up to a maximum of 3 sleep study items per patient in any 12-month period from this item and items XXXXX-1, XXXXX-2, XXXXX-3, XXXXX-4 and XXXXX-6.</p> <p>(See para DN.1.17 of explanatory notes to this Category)</p> <p><b>Fee: \$284.19      Benefit: 75% = \$213.14      85% = \$241.56</b></p>	

**MBS item XXXXX-6**

Overnight investigation of sleep for at least 8 hours, for a patient aged at least 12 years but less than 18 years, to ~~confirm~~ assess adequacy of ~~present~~ respiratory support for obstructive sleep apnoea, if:

- (a) (i) the patient is using Continuous Positive Airway Pressure (CPAP) or other non-invasive ventilation
  - (ii) ~~the patient has been referred by a medical practitioner to~~ a qualified paediatric or adult sleep medicine practitioner has determined that the patient is stable on current respiratory support for sleep disordered breathing; and
  - (iii) following professional attendance ~~of~~ on the patient (either face to face or by video conference) by a qualified paediatric or adult sleep medicine specialist who determines that investigation is necessary to assess respiratory support ~~therapy [CPAP or bilevel]~~; and
- (b) 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);
- (c) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner who is on the staff list of a sleep laboratory accredited under the NATA/ASA Sleep Disorders Service Accreditation Program; and
- (d) either:
  - (i) the equipment is applied to the patient by a sleep technician; or
  - (ii) if this is not possible – the reason it is not possible for the accredited paediatric or adult sleep laboratory professional to apply the equipment to the patient is documented and a ~~health professional~~ parent or caregiver is given instructions on how to apply the equipment by an ~~affiliated~~ accredited sleep laboratory.
- (e) written instructions are given to parent/caregiver to monitor the ~~child~~ patient overnight and a phone contact or data link to the accredited paediatric or adult sleep laboratory to enable trouble shooting overnight if required; and
- (f) polygraphic records are:
  - (i) analysed for assessment of sleep stage, arousals, respiratory events, and cardiac abnormalities using manual scoring, or manual correction of computerised scoring in epochs of not more than 1 minute; and
  - (ii) stored for interpretation and preparation of a report; and
- (g) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine specialist 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
- (h) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203

Up to a maximum of 3 sleep study items per patient in any 12-month period from this item and items XXXXX-1, XXXXX-2, XXXXX-3, XXXXX-4 and XXXXX-5.

(See para DN.1.17 of explanatory notes to this Category)

**Fee: \$284.19      Benefit: 75% = \$213.14      85% = \$241.56**

ASA = Australasian Sleep Association; CO<sub>2</sub> = carbon dioxide; CPAP = continuous positive airway pressure; ECG = electrocardiogram; MBS = Medical Benefits Schedule; NATA = National Association of Testing Authorities  
 Suggested additions are underlined in blue text and deletions are in strikethrough.  
 Source: compiled for this assessment report, adapted from the Ratified PICO confirmation Table 22, Appendix F

## 7. Population

The ratified PICO confirmation specified three PICO Sets. PICO Sets 1 and 2 were for diagnosis of OSA, a disorder of breathing during sleep characterised by airway obstruction.

In adults, the primary association with OSA is obesity. In children, the most common cause is enlargement of the tonsils and adenoids; these grow most quickly in the pre-school years leading

to a peak in OSA incidence in young children. Ear Nose Throat (ENT) surgery, mainly adenotonsillectomy, is the mainstay of initial treatment for paediatric OSA. In-laboratory PSG (Level 1), commonly referred to as a 'sleep study', is the gold standard for diagnosing and quantifying OSA. However, Level 1 PSG may not be readily available, is time consuming and for reimbursement under the MBS must be ordered and assessed by a sleep specialist. Most children undergo tonsillectomy following a clinical diagnosis of OSA rather than having the diagnosis confirmed with PSG.

Children with certain underlying medical conditions, particularly those associated with muscle weakness, hypotonia and craniofacial abnormalities, are more likely to have OSA. Breathing disorders in these children are more complex and likely to be multifactorial so these children have a higher likelihood of residual OSA following treatment and to need repeat or ongoing sleep studies.

### **PICO Set 1**

The proposed population for PICO Set 1 was children and adolescents who have been determined by a qualified sleep medicine practitioner to require PSG confirmation of suspected moderate to severe OSA and for whom an out-of-laboratory setting has been deemed appropriate. The proposed intervention for this population was a Level 2 PSG study for diagnosis of OSA.

The population was uncomplicated patients. High risk patients, defined as those at risk of hypoventilation (including obesity hypoventilation) or with complex co-morbidities (such as heart disease), are not considered suitable for a Level 2 PSG study. The proposed intervention was for the investigation of possible OSA, and the population excluded patients suspected of sleep movement disorders, suspected nocturnal seizures, atypical parasomnias, hypersomnia and narcolepsy, or patients initiating respiratory support.

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

### **PICO Set 2**

Level 3 CRP was proposed for the investigation of suspected moderate to severe 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. As a proxy, the applicant proposed 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 (e.g. patients with neurocognitive conditions such as autism spectrum disorder; also, Rett, Prader-Willi, or Down syndromes).

The Level 3 CRP (diagnostic) was proposed as an additional test because the patient population is defined by an inability to tolerate a Level 1 or Level 2 PSG, therefore the alternative for these patients is no sleep study.

### **PICO Set 3**

Non-invasive respiratory support with continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) is a treatment option for OSA when surgery is not indicated or OSA persists following surgery. Non-invasive respiratory support for OSA is also commonly indicated for children and adolescents with underlying medical conditions such as craniofacial and airway abnormalities or chronic lung disease. Children and adolescents receiving non-invasive respiratory support (CPAP or BiPAP) require routine monitoring 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.

Level 3 CRP (monitoring) was proposed as a replacement test for Level 1 PSG for treatment monitoring of OSA in children and adolescents diagnosed with OSA and stable on BiPAP or CPAP.

The assessment report has addressed the requirements of the ratified PICO confirmation, where evidence was available.

## 8. Comparator

The comparator for PICO Set 1 (Level 2 PSG study (diagnostic)) was a diagnostic Level 1 PSG study under MBS item 12210 for children or 12213 for adolescents. The applicant's clinical claim is that a Level 2 PSG study is non-inferior to a Level 1 PSG study in children and adolescents at risk of significant OSA.

The comparator for PICO Set 2 (Level 3 CRP study (diagnostic)) was no sleep study and standard non-CPAP management based on clinical features alone. The applicant's clinical claim is that a Level 3 CRP is superior to no sleep study and standard management in children and adolescents at risk of significant OSA and intolerant or likely to be intolerant of head leads for a full PSG setup.

The comparator for PICO Set 3 (Level 3 CRP study (monitoring)) is a Level 1 PSG claimed under MBS items 12210, 12213, 12215 and 12217. The applicant's clinical claim is that a Level 3 CRP is non-inferior to a Level 1 PSG study in children and adolescents who are stable on CPAP or BiPAP respiratory support.

## 9. Summary of public consultation input

Consultation input was welcomed from four (4) professional organisations and (1) consumer organisation:

- Australia and New Zealand Sleep Science Association (ANZSSA)
- Thoracic Society of Australia and New Zealand (TSANZ)
- Private Healthcare Australia (PHA)
- Australian Society of Otolaryngology Head and Neck Surgery (ASOHNS) – *Targeted*
- Sleep Health Foundation (SHF)

The consultation feedback received was largely supportive of public funding for out-of-laboratory sleep studies in the diagnosis and management of sleep disordered breathing in children & adolescents.

### Benefits

- Improved access 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
- Sleep and ENT physicians can triage surgery based on clinical need
- Specialists would 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

### Disadvantages

- 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.

- Potential challenges with logistics and damage to equipment
- Risks that come with an unsupervised testing, which may result in participants requiring supplemental testing
- Limitations with lack of video monitoring for at-home studies

#### **Additional comments**

The set-up of paediatric sleep studies, levels 1-4, require specialist training and expertise from the physiologist/nurse setting up the patients given the wide range of ages, maturity, and disease related compliance with the application of the various sensors and electrodes required for differing levels of out-of-laboratory sleep studies.

The risk of signal loss or study failure would be mitigated by testing being restricted to NATA/ASA accredited services with the addition of telephone support.

The risk of lead entanglement can be significantly reduced through documentation of this risk on written materials and requesting parents and carers check on their child periodically during the study.

Only paediatric sleep specialists accredited in Australia should be allowed to request and report the proposed service, and children with failed studies at home may need a repeat study or attend a hospital-based study.

The home sleep service could potentially be commercialised by the private sector.

The eligibility criteria for the overnight pulse oximetry eligibility criteria could be extended to include children 12-18 years of age and living in metropolitan areas.

## **10. Characteristics of the evidence base**

Key features of the included evidence are summarised in Table 6. No direct from test to health outcomes evidence was identified for any PICO set.

For PICO Set 1, two studies (Cielo et al. 2023<sup>2</sup>; Withers et al. 2022<sup>3</sup>) met the inclusion criteria for assessing the test accuracy and reliability (i.e. rate of test failure and repeat tests) of out-of-laboratory Level 2 PSG studies compared to Level 1 PSG studies. These were supplemented with

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<sup>2</sup> Cielo CM, Kelly A, Xanthopoulos M, Pipan M, Arputhan A, Walega R, Ward M, Falvo J et al. (2023) 'Feasibility and performance of home sleep apnea testing in youth with Down syndrome', *Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine*, doi:<https://doi.org/10.5664/jcsm.10610>.

<sup>3</sup> Withers A, Maul J, Rosenheim E, O'Donnell A, Wilson A, and Stick S (2022) 'Comparison of home ambulatory type 2 polysomnography with a portable monitoring device and in-laboratory type 1 polysomnography for the diagnosis of obstructive sleep apnea in children', *Journal of Clinical Sleep Medicine*, 18(2): 393-402, doi:<https://doi.org/10.5664/jcsm.9576>.

five single-arm cohort studies that assessed the test reliability of Level 2 PSG (Goodwin et al. 2001<sup>4</sup>; Griffiths et al. 2022; Ioan et al. 2020<sup>5</sup>; Marcus et al. 2014<sup>6</sup>; Russo 2021<sup>7</sup>).

Five studies were included that assessed the test accuracy of out-of-laboratory Level 3 CRP against the reference standard of Level 1 PSG in a sleep laboratory (Alonso-Álvarez et al. 2015<sup>8</sup>; Ikizoglu et al. 2019<sup>9</sup>; Kissow Lildal et al. 2023; Revana et al. 2022<sup>10</sup>; Fishman et al. 2018<sup>11</sup>). These provided diagnostic accuracy outcomes for PICO Set 2 and 3; however, they did not provide comparative data for PICO Set 2 (comparator is no sleep study) and were in the wrong population for PICO Set 3 (test accuracy may differ in patients using respiratory support during the study). Three of the test accuracy studies also reported test reliability (Kissow Lildal et al. 2023; Fishman et al. 2018; Ikizoglu et al. 2019). An additional four studies were included to assess the test reliability of Level 3 CRP (Kingshott et al. 2019; Brockmann et al.<sup>12</sup> 2016; Chiner et al. 2020<sup>13</sup>; Green et al. 2022<sup>14</sup>).

For PICO Set 2, no studies met the inclusion criteria for change in management; however, one cross-sectional accuracy study (Kissow Lildal et al. 2023) and one comparative cohort study (Chiner et al. 2020) provided data that were considered in the linked evidence approach. The health outcomes of adenotonsillectomy were summarised from two systematic reviews

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<sup>4</sup> Goodwin JL, Enright PL, Kaemingk KL, Rosen GM, Morgan WJ, Fregosi RF, and Quan SF (2001) 'Feasibility of using unattended polysomnography in children for research-report of the tucson children's assessment of sleep apnea study (TuCASA)', *Sleep*, 24(8): 937-944, doi:<https://doi.org/10.1093/sleep/24.8.937>.

<sup>5</sup> Ioan I, Weick D, Schweitzer C, Guyon A, Coutier L, and Franco P (2020) 'Feasibility of parent-attended ambulatory polysomnography in children with suspected obstructive sleep apnea', *Journal of Clinical Sleep Medicine*, 16(7): 1013-1019, doi:<https://doi.org/10.5664/jcsm.8372>

<sup>6</sup> Marcus CL, Traylor J, Biggs SN, Roberts RS, Nixon GM, Narang I, Bhattacharjee R, Davey MJ et al. (2014) 'Feasibility of comprehensive, unattended ambulatory polysomnography in school-aged children', *Journal of Clinical Sleep Medicine*, 10(8): 913-918, doi:<https://doi.org/10.5664/jcsm.3970>.

<sup>7</sup> Russo K, Greenhill J, and Burgess S (2021) 'Home (Level 2) polysomnography is feasible in children with suspected sleep disorders', *Sleep Medicine*, 88: 157-161, doi:<https://doi.org/10.1016/j.sleep.2021.10.024>.

<sup>8</sup> Alonso-Álvarez ML, Terán-Santos J, Ordax Carbajo E, Cordero-Guevara JA, Navazo-Egüia AI, Kheirandish-Gozal L, and Gozal D (2015) 'Reliability of home respiratory polygraphy for the diagnosis of sleep apnea in children', *Chest*, 147(4): 1020-1028, doi:<https://doi.org/10.1378/chest.14-1959>.

<sup>9</sup> Ikizoglu NB, Kiyani E, Polat B, Ay P, Karadag B, and Ersu R (2019) 'Are home sleep studies useful in diagnosing obstructive sleep apnea in children with down syndrome?', *Pediatric Pulmonology*, 54(10): 1541-1546, doi:<https://doi.org/10.1002/ppul.24440>.

<sup>10</sup> Revana A, Vecchio J, Guffey D, Minard CG, and Glaze DG (2022) 'Clinical application of home sleep apnea testing in children: a prospective pilot study', *Journal of Clinical Sleep Medicine*, 18(2): 533-540, doi:<https://doi.org/10.5664/jcsm.9650>.

<sup>11</sup> Fishman H, Massicotte C, Li R, Zabih W, McAdam LC, Al-Saleh S, and Amin R (2018) 'The accuracy of an ambulatory level III sleep study compared to a level I sleep study for the diagnosis of sleep-disordered breathing in children with neuromuscular disease', *Journal of Clinical Sleep Medicine*, 14(12): 2013-2020, doi:<https://doi.org/10.5664/jcsm.7526>.

<sup>12</sup> Brockmann PE, Damiani F, Nuñez F, Moya A, Pincheira E, Paul MA, and Lizama M (2016) 'Sleep-disordered breathing in children with Down syndrome: Usefulness of home polysomnography', *International Journal of Pediatric Otorhinolaryngology*, 83: 47-50, doi:<https://doi.org/10.1016/j.ijporl.2016.01.030>.

<sup>13</sup> Chiner E, Cánovas C, Molina V, Sancho-Chust JN, Vañes S, Pastor E, and Martínez-García MA (2020) 'Home respiratory polygraphy is useful in the diagnosis of childhood obstructive sleep apnea syndrome', *Journal of Clinical Medicine*, 9(7): 1-13, doi:<https://doi.org/10.3390/jcm9072067>.

<sup>14</sup> Green A, Nagel N, Kemer L, and Dagan Y (2022) 'Comparing in-lab full polysomnography for diagnosing sleep apnea in children to home sleep apnea tests (HSAT) with an online video attending technician', *Sleep and Biological Rhythms*, 20(3): 397-401, doi:<https://doi.org/10.1007/s41105-022-00384-7>.

(Venekamp et al. 2015<sup>15</sup>; Francis et al. 2017<sup>16</sup>) and applicability of the evidence to the proposed patient population was discussed based on four studies incidentally retrieved from the literature search (Lanzlinger et al. 2023<sup>17</sup>; Primeau et al. 2016<sup>18</sup>; Jones et al. 2023<sup>19</sup>; Luong et al. 2023<sup>20</sup>).

For PICO Set 3, no studies met the inclusion criteria for any outcome. A single case series (Amaddeo et al. 2015<sup>21</sup>) was included that reported change in management outcomes. The study was undertaken in a laboratory setting.

**Table 6 Key features of the included evidence**

Criterion	Type of evidence supplied	Extent of evidence supplied	Overall risk of bias in evidence base
Accuracy of the test (cross-sectional accuracy)	Cross-sectional diagnostic accuracy studies of index test compared to reference standard. Reference standard is also the comparator for PICO Set 1 and 3. For PICO Set 2 no comparative evidence was identified.	PICO Set 1 <input checked="" type="checkbox"/> k = 2 n = 87 PICO Set 2 & 3 <input checked="" type="checkbox"/> k = 5 n = 169	QUADAS-2: overall most studies had moderate risk of bias
Test reliability	Comparative and single arm studies	PICO Set 1 Comparative studies: <input checked="" type="checkbox"/> k = 2 n = 87 Single arm studies: <input checked="" type="checkbox"/> k = 5 n = 708 PICO Set 2 & 3 Comparative studies: <input checked="" type="checkbox"/> k = 5 n = 190 Single arm studies: <input checked="" type="checkbox"/> k = 2 n = 402	NHLBI quality assessment tool for case series studies: Low risk in two studies, moderate to high risk in the remainder

<sup>15</sup> Venekamp RP, Hearne BJ, Chandrasekharan D, Blackshaw H, Lim J, and Schilder AGM (2015) 'Tonsillectomy or adenotonsillectomy versus non-surgical management for obstructive sleep-disordered breathing in children', *Cochrane Database of Systematic Reviews*, 2015(10),

<sup>16</sup> Francis DO, Chinnadurai S, Sathe NA, Morad A, Jordan AK, Krishnaswami S, Fannesbeck C, and McPheeters ML. (January 2017). Tonsillectomy for Obstructive Sleep-Disordered Breathing or Recurrent Throat Infection in Children. In *Comparative Effectiveness Reviews*, No. 183. . Agency for Healthcare Research and Quality (US).

<sup>17</sup> Lanzlinger D, Kevat A, Collaro A, Poh SH, Pérez WP, and Chawla J (2023) 'Tolerance of polysomnography in children with neurodevelopmental disorders compared to neurotypical peers', *J Clin Sleep Med*, 19(9): 1625-1631, doi:<https://doi.org/10.5664/jcsm.10626>.

<sup>18</sup> Primeau M, Gershon A, Talbot L, Cotto I, Lotspeich L, Hardan A, Hallmayer J, and O'Hara R (2016) 'Individuals with Autism Spectrum Disorders Have Equal Success Rate But Require Longer Periods of Systematic Desensitization than Control Patients to Complete Ambulatory Polysomnography', *J Clin Sleep Med*, 12(3): 357-362, doi:<https://doi.org/10.5664/jcsm.5584>.

<sup>19</sup> Jones S, Hanwell R, Chowdhury T, Orgill J, Van Den Eshof K, Farquhar M, Joseph D, Gringras P et al. (2023) 'Feasibility and parental perception of home sleep studies during COVID-19: A tertiary sleep centre experience', *Archives of Disease in Childhood*, doi:<https://doi.org/10.1136/archdischild-2021-322184>.

<sup>20</sup> Luong S, Culp M, McCreary M, Wani A, and Caraballo M (2023) 'Reasons and predictors for early termination of pediatric polysomnography: one children's hospital's experience', *Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine*, doi:<https://doi.org/10.5664/jcsm.10646>.

<sup>21</sup> Amaddeo A, Caldarelli V, Fernandez-Bolanos M, Moreau J, Ramirez A, Khirani S, and Fauroux B (2015) 'Polygraphic respiratory events during sleep in children treated with home continuous positive airway pressure: Description and clinical consequences', *Sleep Medicine*, 16(1): 107-112, doi:<https://doi.org/10.1016/j.sleep.2014.07.030>.

Criterion	Type of evidence supplied	Extent of evidence supplied	Overall risk of bias in evidence base
Change in patient management	No studies met the inclusion criteria for PICO Set 1. No studies met the inclusion criteria for PICO Set 2. One cross-sectional accuracy study and one comparative cohort study provided limited information. One single-arm case series was included for PICO Set 3.	PICO Set 3 ☒ k = 1 n = 26	NHLBI quality assessment tool for case series studies: significant applicability concerns, low risk of bias
Health outcomes	No studies met the inclusion criteria for direct evidence. Two systematic reviews were identified to provide information of treatment effectiveness for PICO Set 2.	PICO Set 2 ☒ k = 2 SR n = 16,316	Not done as studies did not meet inclusion criteria
Safety	One PICO Set 1 single-arm cohort study reported safety of the test. No other studies met the inclusion criteria for safety outcomes.	PICO Set 1 ☒ k = 1 n = 233	NHLBI quality assessment tool for case series studies: Low risk
Other	Four additional studies to explore the patient population in PICO Set 2.	PICO Set 2 ☒ k = 4 n = 665	Not done as studies did not meet inclusion criteria

k = number of studies; n = number of patients; NHLBI = National heart, lung, and blood institute; PICO = population, intervention, comparator, outcome; SR = systematic review; QUADAS-2 = quality assessment of diagnostic accuracy studies tool for comparison of an index test with a reference standard.

As already noted by both the applicant and PASC, evidence to support out-of-laboratory sleep studies in adolescents was extremely limited. Support for use in this age group relied on extrapolation from evidence collected in the younger (under 12 years) age group. Evidence to support PICO Set 3 was inadequate to support an economic evaluation. The extent and level of clinical evidence overall was considered unlikely to change given that paediatric out-of-laboratory sleep studies is a niche indication.

## 11. Comparative safety

No comparative studies met the inclusion criteria and reported safety outcomes. One included study, Griffiths et al. (2022), an Australian single-arm, single-centre, retrospective audit of Level 2 PSG studies (diagnostic), reported no adverse events during the study period.

No paediatric safety data were reported in MSAC application 1130 (Merlin et al. 2010<sup>22</sup>) and the report concluded that out-of-laboratory sleep studies (of any level) are safe. Similarly, the ASA clinical practice guidelines for sleep studies in children states that although safety concerns have not been identified, attention to safety is required for unattended studies, particularly adequate parental instruction and monitors set up by trained staff (Pamula et al. 2017<sup>23</sup>). Although no data were identified for Level 3 CRP (diagnostic or monitoring studies), it is inferred to have a lower risk due to reduced equipment requirements.

<sup>22</sup> Merlin T, Lifu Z, and Wang S. (June 2010). Unattended sleep studies in the diagnosis and reassessment of obstructive sleep apnoea. In MSAC Application No. 1130. Medical Services Advisory Committee, Department of Health.

<sup>23</sup> Pamula Y, Nixon GM, Edwards E, Teng A, Verginis N, Davey MJ, Waters K, Suresh S et al. (2017) 'Australasian Sleep Association clinical practice guidelines for performing sleep studies in children', *Sleep Med*, 36 Suppl 1: S23-S42, doi:<https://doi.org/10.1016/j.sleep.2017.03.020>.



Theoretically, there could be a difference in exposure to nosocomial respiratory infections for out-of-laboratory settings compared to in-laboratory settings, but no data are available. This may have heightened relevance to PICO Set 3 due to the high rate of complex co-occurring conditions in individuals receiving respiratory support.

Only PICO Set 2 is likely to alter the downstream treatment decisions based on the diagnostic assessment frameworks. There is a theoretical benefit of the Level 3 CRP (diagnostic) from avoiding inappropriate tonsillectomies and the attendant risk of harms; these harms are low frequency and rarely require readmission or reoperation (Francis et al. 2017).

## 12. Comparative effectiveness

### PICO Set 1

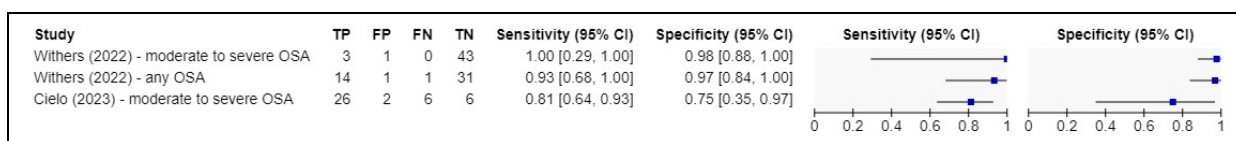
#### Test accuracy

Two studies (Cielo et al. 2023; Withers et al. 2022) reported test accuracy of Level 2 PSG studies compared to Level 1 PSG studies.

Withers et al. (2022) was an Australian study with a population of 47 children aged 5 to 18 years with suspected OSA, closely aligned with the PICO age range of 3 to 18 years. At both reported thresholds – any OSA and moderate to severe OSA – the Level 2 PSG misclassified very few participants in comparison to the Level 1 PSG, and sensitivity and specificity were both high with confidence intervals including perfect agreement (GRADE certainty of evidence very low) (Figure 1).

Participants in Cielo et al. (2023) (n=43) had Down syndrome, were not required to be seeking evaluation of SDB and were aged up to 25 years. The prevalence of moderate to severe OSA was 80%. Diagnostic accuracy for Level 2 PSG was lower in this study (Figure 1). This might be explained by both the older age range (where diagnostic thresholds are higher) and the higher prevalence of severe disease (where correlation between the tests is poorer). Some study participants may not be considered suitable for Level 2 PSG based on the PICO confirmation, which excludes participants with complex co-morbidities.

**Figure 1 Forest plot of diagnostic accuracy of Level 2 PSG studies with Level 1 PSG studies as the reference standard**



CI = confidence interval; FN = false negative; FP = false positive; OAHl = obstructive apnoea-hypopnoea index; OSA = obstructive sleep apnoea; PSG = polysomnography; TN = true negative; TP = true positive.

Notes: Withers did not report the AHI/OAHl values used for each diagnostic threshold. Moderate to severe OSA in Cielo (2023) was OAHl > 5/h.

Source: created for the DCAR using data from Table 45.

#### Test reliability

No difference in test failures was reported between Level 1 PSG (range 0-5%) and Level 2 PSG (range 0-7%) in the two cross-sectional accuracy studies. An additional five single-arm studies reported initial Level 2 test failure rates ranging from 9-19% (Goodwin et al. 2001; Griffiths et al. 2022; Ioan et al. 2020; Marcus et al. 2014; Russo 2021).

## Change in management

No change in management studies were identified that met the inclusion criteria, nor are they necessary for a truncated assessment framework.

The applicant indicated that treatment decisions following PSG are not made based on the PSG findings alone and incorporate symptoms, physical findings (such as tonsil and adenoid size), and patient and caregiver preferences. Therefore, the impact of any differential findings between Level 1 and Level 2 PSG is likely to be less than indicated based on test accuracy alone as clinical management decisions are driven by a broader set of factors.

The technical interpretation of Level 1 and Level 2 PSG for the diagnosis of OSA does not differ and they evaluate the same measures in the same way. It is plausible to assume that a diagnosis of OSA (or otherwise) will lead to the same treatment decisions regardless of how it is reached.

## Clinical claim

The use of Level 2 PSG studies results in non-inferior test accuracy compared with Level 1 PSG studies.

The use of Level 2 PSG studies results in inferior testing success compared with Level 1 PSG studies. This may well be offset by the convenience to patients and caregivers of undertaking testing in a home environment.

The use of Level 2 PSG studies results in non-inferior effectiveness compared with Level 1 PSG studies.

The use of out-of-laboratory Level 2 PSG studies results in non-inferior safety compared with Level 1 PSG studies.

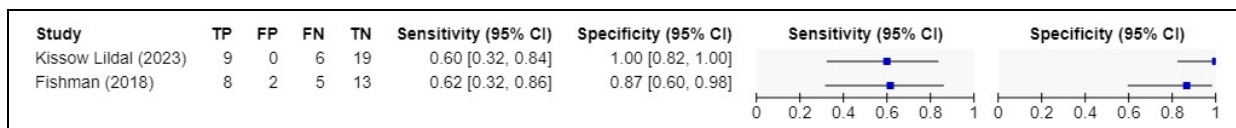
## PICO Set 2

### Test accuracy

Five small studies (Alonso-Álvarez et al. 2015 [n=50]; Ikizoglu et al. 2019 [n=19]; Kissow Lildal et al. 2023 [n=34]; Revana et al. 2022 [n=38]; Fishman et al. 2018 [n=28]) reported the test accuracy of Level 3 CRP against the reference standard of Level 1 PSG. Three of these studies adjusted the diagnostic threshold for Level 3 CRP relative to Level 1 PSG to maximise diagnostic accuracy (Level 3 CRP threshold adjusted upwards in two and downwards in one).

Two studies reported diagnostic accuracy for the diagnosis of moderate to severe OSA, one in participants scheduled for (adeno)tonsillotomy (Kissow Lildal et al. 2023) and one in participants with neuromuscular disease (Fishman et al. 2018). The specificity in these studies was high (range 87% to 100%), while the sensitivity was modest (range 60% to 62%) (Figure 2).

**Figure 2 Forest plot of diagnostic accuracy of Level 3 CRP with Level 1 PSG as the reference standard for a diagnosis of moderate to severe OSA**



CI = confidence interval; CRP = cardiorespiratory polygraphy; FN = false negative; FP = false positive; OSA = obstructive sleep apnoea; PSG = polysomnography; TN = true negative; TP = true positive.

The prevalence of OSA in the population in Kissow Lildal et al. (2023) is similar to the estimated prevalence in the PICO population (76% any OSA and 44% moderate to severe). The study

reported a positive predictive value of 95% (95% CI: 76 - 100) for any OSA and 100% (95% CI: 66 - 100) for moderate to severe OSA, therefore Level 3 CRP can rule-in OSA. However, the negative predictive value was 54% (95% CI: 36 - 71) for any OSA and 76% (95% CI: 63 - 85) for moderate severe OSA, suggesting that a negative test result does not accurately rule-out OSA (GRADE certainty of evidence very low).

Level 3 CRP is proposed as an additional test to no sleep study and standard non-CPAP management. Although no studies reported on the diagnostic accuracy of the comparator, all participants are implied to be positive for OSA based on clinical and physical features, with the included studies presenting the additional value of a Level 3 CRP. This is most clearly demonstrated in Kissow Lildal et al. (2023), as all participants underwent tonsillectomy based on symptoms.

### ***Test reliability***

Five studies reported test failures of Level 3 CRP compared to Level 1 PSG; two studies in a general population (Green et al. 2022 [n=100]; Kissow Lildal et al. 2023 [n=53]), two in children and adolescents with Down syndrome (Brockmann et al. 2016 [n=44]; Ikizoglu et al. 2019 [n=19]) and one in children with neuromuscular disease (Fishman et al. 2018 [n=28]). The rate of Level 3 CRP test failure ranged from 8 to 19% and the rate of Level 1 PSG test failure ranged from 0 to 8%. In the five comparative studies, no statistical difference was observed between Level 3 CRP and Level 1 PSG test failure rates; however, all studies were small and are expected to be underpowered for this outcome.

Similar rates of Level 3 CRP test failures were reported in two larger single-arm cohorts (Chiner et al. (2020) [n=104]; Kingshott et al. (2019) [n=255]: 9-26%).

### ***Change in management***

Although no studies met inclusion criteria for change in management, Kissow Lildal et al. (2023) provides theoretical changes based on test outcomes as the participants had symptoms indicative of OSA and all had tonsillectomy with or without adenoidectomy based on “treatment as usual”. Of 34 participants, Level 3 CRP classified 15 as negative for moderate to severe OSA (6 false negatives and 19 true negatives). False negative classification may lead to a patient missing out on an appropriate tonsillectomy; however, this depends on clinical symptoms. One of the six false negative participants was negative for any OSA (AHI<1). True negative patients may avoid inappropriate tonsillectomy; however, appropriateness depends on clinical symptoms for mild OSA (AHI 1-5). Of the 15 negatives for moderate to severe OSA, 7 were correctly classified with no OSA and are most likely to avoid inappropriate tonsillectomy.

### ***Health outcomes***

Two systematic reviews were used to summarise the health outcomes of adenotonsillectomy for OSA in paediatric populations (Venekamp et al. 2015 [k=3]; Francis et al. 2017 [k=213]). For patients with OSA determined by Level 1 PSG, adenotonsillectomy resulted in improvement in quality of life, and symptoms were statistically significant at 7 months’ follow-up (GRADE certainty of evidence moderate) while neurocognitive performance and attention and executive function were similar in both groups (GRADE certainty of evidence high). PSG recordings had normalised in almost half of the children managed non-surgically. The most common post-surgical complication was post-tonsillectomy haemorrhage (frequency at or below 5%).

### ***Patient population***

None of the included studies specifically included the patient population defined in the PICO confirmation: intolerant of head leads, including those with severe behavioural issues, sensory intolerance and/or autism spectrum disorder. Four studies identified in the literature search

specifically addressed this population, however they were not systematically identified and were described to provide context.

The additional evidence highlighted that there are participants who have difficulty tolerating sleep studies, including Level 3 CRP (Jones et al. 2023) (n=96); this is more common in participants with neurodevelopmental disorders, although intolerance was also strongly associated with younger age (Lanzlinger et al. 2023 [n=271, aged 1 to 18]; Primeau et al. 2016 [n=161, aged 3 to 25]). Tolerance of nasal prongs, used in Level 3 CRP, appeared to be lower than head leads. The ability to tolerate the test appears to be dependent not only on the test itself, but also on the procedures in place to assist patients who have sensitivities to the equipment. Therefore, there is uncertainty in linking the evidence identified to the specified patient population particularly with respect to failure rates. Higher failure rates are likely, with the rate of 26% failure at first attempt and 19% at second attempt as reported for the cohort of participants with Down syndrome by Kingshott et al. (2019) perhaps forming the baseline.

The population for PICO Set 2 is difficult to define as it is not specific to particular medical conditions. There is a risk that the population who access a Level 3 CRP under the proposed MBS item may differ to that intended in the application, with the potential for usage outside the intended population.

### ***Clinical claim***

The use of Level 3 CRP results in inferior test accuracy compared with Level 1 PSG. Test accuracy is inferred to be superior compared with no sleep study (clinical diagnosis based on history and physical features), but no direct comparative evidence was available.

The use of Level 3 CRP is inferred to be superior in effectiveness compared with no sleep study based on theoretical changes to patient management following Level 3 CRP.

Testing success is unknown in the proposed patient population and anticipated to vary depending on patient and organisational factors.

The use of out-of-laboratory Level 3 CRP results in non-inferior safety compared with no sleep study and standard non-CPAP management. The use of Level 3 CRP may improve patient selection for tonsillectomy, which could lead to safer treatment outcomes.

### **PICO Set 3**

#### ***Test accuracy***

No studies were identified that met the inclusion criteria for assessing the test accuracy of out-of-laboratory Level 3 CRP used to monitor therapy in children and adolescents receiving respiratory support compared to Level 1 PSG monitoring every 6 months. Test accuracy for this indication was inferred from the five studies included in PICO Set 2; it is unknown whether test accuracy would differ for sleep studies undertaken with the patient using respiratory support.

There is no agreement on the objective or acceptable levels of respiratory events and their clinical consequences for children undergoing non-invasive ventilation (Ammadeo et al. 2015). It is anticipated that treated patients on stable non-invasive ventilation would tend to have no or mild residual disease. For the classification of moderate to severe OSA, the diagnostic accuracy studies demonstrated high specificity. The ability to rule-in moderate or severe OSA may be appropriate for monitoring, with the consequent risk that some negative findings will be false negatives. These may be detected in subsequent monitoring scheduled at six-monthly intervals or sooner for some patients.

### ***Change in management***

A single study, Ammadeo et al. (2015), was included for assessing change in management following a Level 3 CRP study for monitoring respiratory support (CPAP or BiPAP) in children and adolescents with SDB who are stable on current respiratory support. This small (n=26) single-arm study performed Level 3 CRP in a dedicated sleep unit in a paediatric hospital, not in an out-of-laboratory setting as required by the PICO criteria.

In total, adjustments to respiratory support were made in seven cases (25% of patients) following in-laboratory Level 3 CRP, most commonly an increase in the CPAP level (3 participants). The single-arm study provides no information on how these treatment decisions may differ to those that would be made following a Level 1 PSG.

Based on reduced accuracy, particularly sensitivity, it is possible that some changes, particularly the need for increases in CPAP levels, will be missed. As monitoring is a periodic activity, residual OSA may be detected at a later time point and CPAP changes made then.

### ***Health outcomes***

No studies met inclusion criteria for assessing the health outcomes of out-of-laboratory Level 3 CRP used to monitor therapy in children and adolescents receiving respiratory support. Monitoring appears to be widely recommended in guidelines for children receiving home-based non-invasive ventilation despite a paucity of evidence that it improves health outcomes.

### ***Additional considerations***

Two additional studies of cohorts of paediatric patients receiving respiratory support did not meet inclusion criteria for the assessment but provide information regarding the likely patient population (Tan et al. 2007<sup>24</sup> [n=45]; Widger et al. 2014<sup>25</sup> [n=42]). The relevant population is varied and has a range of frequently severe co-occurring conditions, particularly craniofacial syndromes and neuromuscular diseases. This needs to be considered when the potential benefits of Level 3 CRP are considered with respect to practicality; for patients and their families the benefits of avoiding a hospital stay may be significant when the patients have complex, ongoing medical conditions.

### ***Clinical claim***

The use of Level 3 CRP to monitor therapy in children and adolescents receiving respiratory support results in uncertain effectiveness compared with Level 1 PSG.

The use of Level 3 CRP to monitor therapy in children and adolescents receiving respiratory support results in uncertain safety compared with Level 1 PSG.

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<sup>24</sup> Tan E, Nixon GM, and Edwards EA (2007) 'Sleep studies frequently lead to changes in respiratory support in children', *Journal of Paediatrics and Child Health*, 43(7-8): 560-563, doi:<https://doi.org/10.1111/j.1440-1754.2007.01138.x>.

<sup>25</sup> Widger JA, Davey MJ, and Nixon GM (2014) 'Sleep studies in children on long-term non-invasive respiratory support', *Sleep and Breathing*: 1-5, doi:<https://doi.org/10.1007/s11325-014-0960-6>.

## 13. Economic evaluation

### PICO Set 1

A cost-minimisation analysis was undertaken.

Table 7 provides a summary of the approach taken for the PICO Set 1 economic evaluation.

**Table 7 Summary of the economic evaluation**

Component	Description
Therapeutic claim: effectiveness	Based on evidence presented, effectiveness is assumed to be non-inferior
Therapeutic claim: safety	Based on evidence presented, safety is assumed to be non-inferior
Evidence base	Evidence from non-randomised studies
Direct health technology costs	Lower than costs of comparator
Other costs or cost offsets	Equivalent to the costs of comparator

The costs considered were from a health system perspective, outlined in Table 8. The direct health technology costs considered were for the out-of-laboratory Level 2 PSG (intervention) or in-laboratory Level 1 PSG (comparator) sleep study. Additional costs were the same in both arms.

**Table 8 Summary of the costs included in the cost-minimisation approach**

Parameter	Value	Source
<b>Direct health technology costs</b>		
Cost of Level 2 PSG (intervention)	406.15	Weighted average assuming 81.5% in children, 18.5% in adolescents (based on MBS claiming data for items 12210 and 12213, respectively, for FY 2022–23)
Cost of Level 1 PSG (comparator)	754.60	Weighted average assuming 81.5% in children, 18.5% in adolescents (based on MBS claiming data for items 12210 and 12213, respectively, for FY 2022–23)
<b>Additional costs and/or cost offsets</b>		
Initial consult with general practitioner	79.70	MBS Item 36, October 2023.
Consultant physician attendance, initial	293.40	MBS Item 132, October 2023. Chosen based on MBS items for previous MSAC application 1130. Alternative value is MBS Item 110, October 2023
Consultant physician attendance, follow-up	146.90	MBS Item 133, October 2023. Alternative value is MBS Item 116, October 2023

MBS = Medicare Benefits Schedule; PSG = polysomnography.

The base case results for PICO Set 1 are presented in terms of cost per accurate diagnosis, accounting for the risk of incorrect diagnosis among the intervention group, and the costs of repeat testing because of failure of an initial test. Level 2 PSG has a lower cost per accurate diagnosis than Level 1 PSG (Table 9).

**Table 9 Results of cost-minimisation approach for PICO Set 1**

	Initial testing costs	Repeat testing (1)	Repeat testing (2)	Total cost	Cost per diagnosis	Proportionate accurate diagnoses	Cost per accurate diagnosis
Intervention	926.15	72.73	5.41	1,004.29	2,510.73	0.99	2,541.22
Comparator	1,274.60	0.00	0.00	1,274.60	3,186.51	1.00	3,186.51
Difference (intervention – comparator)	-348.45	72.73	5.41	-270.31	-675.78	-0.01	<b>-645.29</b>

In one-way sensitivity analysis, the intervention was cost-saving under all analyses with the exception of where the lower limit of sensitivity was set to 0.29 (compared with 1.00 in the base case analysis) where the cost was \$379.87 higher for the Intervention (Table 11).

**Table 10 Key drivers of the model**

Description	Method/Value	Impact
		Base case: <b>-\$645.29</b> difference in cost per accurate diagnosis
Sensitivity of Level 2 PSG	Estimated as 1 in the base case analysis, with lower limit of 0.29 tested in a sensitivity analysis.	<i>Moderate, favours comparator</i>  <i>Use of lower sensitivity value increased the cost per accurate diagnosis to \$379.87 more expensive for the intervention, relative to the comparator</i>
Variation in expected prevalence	Varied from 20 to 60% in a sensitivity analysis, 40% for the base case.	<i>High, favours intervention</i>  <i>Use of lower prevalence value (20%) decreased the cost per accurate diagnosis to -\$1,269.91 less expensive for the intervention versus the comparator</i>

PSG = polysomnography

**Table 11 Key sensitivity analyses for cost-minimisation approach for PICO Set 1**

Sensitivity analysis scenario	Cost per accurate diagnosis (intervention)	Cost per accurate diagnosis (comparator)	Difference (intervention – comparator)
<b>Base case analysis</b>	<b>2,541.22</b>	<b>3,186.51</b>	<b>-645.29</b>
All Level 2 PSG in children 3 to < 12 years <sup>a</sup>	2,566.45	3,186.51	-620.06
All Level 2 PSG in adolescents 12 to < 18 years <sup>a</sup>	2,430.07	3,186.51	-756.43
All Level 1 PSG in children 3 to < 12 years <sup>a</sup>	2,543.22	3,221.75	-678.53
All Level 1 PSG in adolescents 12 to < 18 years <sup>a</sup>	2,532.42	3,031.25	-498.83
Lower limit of sensitivity (0.29, base 1)	3,566.37	3,186.51	379.87
Lower limit of specificity (0.88)	2,705.52	3,186.51	-480.98
Upper limit of specificity (1, base 0.98)	2,510.73	3,186.51	-675.78
Prevalence 20% (baseline 40%)	5,103.10	6,373.02	-1,269.91
Prevalence 60% (baseline 40%)	1,687.32	2,124.34	-437.02
'Any OSA' as treatment threshold (sensitivity 93%, specificity 97%, prevalence 60%)	1,769.36	2,124.34	-354.97

OSA=obstructive sleep apnoea; PSG = polysomnography.

<sup>a</sup> The base case scenario assumes 18.5% adolescents and 81.5% children, with different costs for these two age groups. The sensitivity analyses test the importance of this assumption. The intervention price changes with the sensitivity analysis applied to the comparator group only because the retesting for failed Level 2 studies is assumed to be 50% Level 1 and 50% Level 2 studies.

## PICO Set 2

A cost-effectiveness analysis was undertaken for PICO Set 2. The economic evaluation was aimed at assessing if Level 3 CRP were cost-effective in terms of cost per tonsillectomy avoided when compared to clinician assessment without a Level 3 study. Although it would have been ideal to express effectiveness in terms of appropriate and inappropriate tonsillectomies, this was not possible due to the limited available information. A summary of the approach is provided in Table 12. The use of CPAP was not considered in the analysis, though Chiner et al. (2020) indicated that approximately 7% of those diagnosed with moderate-severe OSA would require CPAP.

**Table 12 Summary of the economic evaluation**

Component	Description
Perspective	Health care system perspective
Population	Children aged 3 to < 12 together with adolescents aged 12 to < 18 years at risk for significant OSA, and intolerant or likely to be intolerant to head leads for PSG set up
Prior testing	No prior testing assumed
Comparator	Comparator is no sleep study and clinician assessment (assumed to be an ENT surgeon), with initial referral through a general practitioner
Type(s) of analysis	Cost-effectiveness analysis as no appropriate utility values were identified in a systematic review Cost per accurate diagnosis included as a supplementary analysis
Outcomes	Tonsillectomies avoided, unable to classify as 'appropriate' or 'inappropriate'
Time horizon	1 year
Computational method	Decision tree analysis
Generation of the base case	Based on data from non-randomised studies and with clinical input where no data were available
Health states	No specific health states, rather passage through the diagnostic process assumed to end in the outcome of 'tonsillectomy' or 'no tonsillectomy'
Cycle length	Not applicable, due to the short time horizon time not formally considered in the decision tree analysis
Transition probabilities	Based on data from non-randomised studies and with clinical input where no data were available
Discount rate	Given the one year time horizon, no discounting of costs or benefits
Software	TreeAge Pro, inputs/results displayed in Microsoft Excel

ENT = ear, nose and throat; OSA = obstructive sleep apnoea, PSG = polysomnography.

A decision tree was constructed simulating the passage of children and adolescents at significant risk of OSA to either Level 3 CRP (intervention) or to no sleep study (comparator). The transition probabilities were derived from non-randomised studies and where no published data were available, expert opinion. A summary of the inputs for the cost-effectiveness analysis are provided in Table 13.



**Table 13 Summary of the inputs used in the economic evaluation**

Parameter	Value	Source
<b>Transition probabilities</b>		
Expected prevalence	40%	Assumption – clinical experts
Sensitivity – intervention	60%	Kissow Lidal et al. 2023
Specificity – intervention	100%	Kissow Lidal et al. 2023
True positive – intervention	24%	Calculated, prevalence * sensitivity
False positive – intervention	0%	Calculated, (1 – specificity) * (1 – prevalence)
True negative – intervention	60%	Calculated, specificity * (1 – prevalence)
False negative – intervention	16%	Calculated, (1 – sensitivity) * prevalence
Level 3 CRP technical failure or inconclusive test	15%	Included studies (see Section 2, Table 58 and Table 59)
Second Level 3 CRP technical failure or inconclusive test	9%	Assumption
Third Level 3 CRP technical failure or inconclusive test	6%	Assumption
Retesting if technical failure or inconclusive	50%	Assumption, 0 if 3 failures
Tonsillectomy if positive diagnosis from sleep study	76%	Chiner et al. 2020
Tonsillectomy if assessed by ENT surgeon	50%	Assumption
Sensitivity – comparator	80%	Evans et al. 2023
Specificity – comparator	50%	Evans et al. 2023
True positive – comparator	32%	Calculated, prevalence * sensitivity
False positive – comparator	30%	Calculated, (1 – specificity) * (1 – prevalence)
True negative – comparator	30%	Calculated, specificity * (1 – prevalence)
False negative – comparator	8%	Calculated, (1 – sensitivity) * prevalence
Tonsillectomy if positive diagnosis from clinical assessment	100%	Assumption
<b>Costs</b>		
<b>Intervention</b>		
Initial cost with general practitioner	79.70	MBS item 36, October 2023
Consultant physician attendance, initial	293.40	MBS item 132, October 2023
Consultant physician attendance, follow-up	146.90	MBS item 133, October 2023
Cost of Level 3 CRP study	284.19	DCAR, Appendix F
<b>Total costs intervention</b>	<b>804.19</b>	<b>Calculated</b>
<b>Comparator</b>		
Initial consult with general practitioner	79.70	MBS item 36, October 2023
Specialist attendance, initial	95.10	MBS item 104, October 2023
<b>Total costs comparator</b>	<b>174.80</b>	
<b>Tonsillectomy (willingness to pay indicator)</b>		
Professional fee – surgeon	339.21	MBS items 41789 (< 12 years) and 41793 (≥ 12 years), October 2023. Weighted average assuming 81.5% in children, 18.5% in adolescents (based on MBS claiming data for items 12210 and 12213, respectively, for FY 2022–23).

Parameter	Value	Source
Pre-anaesthesia consultation	47.80	MBS item 17610, October 2023
Anaesthesia initiation	130.20	MBS item 20320, 20170 October 2023
Anaesthesia time units	43.40	MBS item 23025, October 2023
Hospital facility services	2,113.00	Total average charge per AR-DRG V10 Private Hospital Data Bureau (2021-22) D11Z – tonsillectomy and/or adenoidectomy
Specialist attendance, follow-up	47.80	MBS item 105, October 2023
<b>Total</b>	<b>2,721.41</b>	

AR-DRG = Australian-Refined Diagnosis Related Groups; CRP=cardiorespiratory polygraphy; ENT, ear, nose and throat; MBS = Medicare Benefits Schedule.

As the outcome of interest for the cost-effectiveness analysis was tonsillectomies avoided, the cost of tonsillectomy was used to set a 'willingness-to-pay' threshold for the intervention. This meant that though all costs leading up to the day of surgery were considered for both groups, the cost of tonsillectomy itself was not included in the model. Using this approach, if the incremental cost per tonsillectomy avoided is less than the cost of a tonsillectomy, the intervention can be considered cost-effective.

The base-case incremental cost per tonsillectomy avoided of \$1,751.65 was less than the expected cost per tonsillectomy (\$2,721.41) meaning that the intervention can be considered to be cost-effective by this measure (Table 14). The economic evaluation highlights that the higher specificity, and lower sensitivity, of Level 3 CRP in comparison to no sleep study (clinic evaluation, potentially aided by sleep questionnaires) may lead to lower false positives, and higher false negatives, and therefore potentially fewer tonsillectomies.

**Table 14 Base case economic evaluation results for PICO Set 2**

	Costs	Tonsillectomies avoided	Cost/ tonsillectomy avoided
Intervention	881.09	0.78	-
Comparator	174.80	0.38	-
Incremental	706.29	0.4	1,751.65

Applying the same method as for PICO set 1, the costs per accurate diagnosis for the intervention and comparator were also estimated. The cost per accurate diagnosis for Level 3 CRP was \$2,537.20 and for no sleep study \$704.84 (difference of \$1,832.36), hence the use of Level 3 CRP is more expensive per accurate diagnosis compared to no testing.

Several one-way sensitivity analyses were performed. The key drivers of the model are presented in Table 15 and sensitivity analysis in Table 16. As the model does not consider appropriate or inappropriate tonsillectomy, some lower incremental cost scenarios may be clinically unfavourable as, for example, when higher rates of false negatives lead to fewer tonsillectomies.

**Table 15 Key drivers of the model**

Description	Method/Value	Impact Base case: \$1,751.65/tonsillectomy avoided
Prevalence, specificity of comparator	Applicant estimated that 50% of patients assessed by the ENT would go onto tonsillectomy. DCAR uses estimated sensitivity and specificity of clinical evaluation combined with sleep questionnaires. Actual estimates may vary by provider.	<i>Higher prevalence of 100% in at risk population led to a higher ICER (\$2,367.29/tonsillectomy avoided) Higher specificity of clinical evaluation of 65% (base case = 50%) increased the ICER (\$2,205.18/tonsillectomy avoided)</i>
Transition probability – sensitivity	Taken from Kissow Lildal et al. (2023), base case of 60%. Limited evidence base and small study.	<i>Moderate; favours Level 3 CRP at lower values however may also result in unfavourable clinical outcome of appropriate tonsillectomies being avoided (higher false negative rate) Use of 33% decreased the incremental cost to \$1,447.38/ tonsillectomy avoided.</i>

CRP=cardiorespiratory polygraphy; ENT=ear, nose and throat.

**Table 16 Key sensitivity analyses for PICO Set 2**

Scenario	Incremental costs	Incremental effectiveness	Incremental cost per tonsillectomy avoided
<b>Base case analysis</b>	<b>706.29</b>	<b>0.4</b>	<b>1,751.65</b>
Expected prevalence among at-risk group of 30% (base = 40%)	698.95	0.42	1,673.77
Expected prevalence among at-risk group of 50% (base = 40%)	713.63	0.39	1,835.29
Expected prevalence among at risk group of 100% (base = 40%)	750.36	0.32	2,367.29
Sensitivity lower limit of 33% (base = 60%)	693.07	0.48	1,447.38
Sensitivity upper limit of 82% (base = 60%)	717.06	0.34	2,099.19
Specificity lower limit of 82% (base = 100%)	719.51	0.33	2,196.41
Tonsillectomy if positive Level 3 study of 50% (base = 76%)	696.24	0.46	1,511.23
Tonsillectomy if positive Level 3 study of 100% (base = 76%)	715.57	0.35	2,043.66
Sensitivity (comparator) lower limit of 75% (base = 80%)	706.29	0.38	1,835.54
Sensitivity (comparator) upper limit of 85% (base = 80%)	706.29	0.42	1,675.09
Specificity (comparator) lower limit of 35% (base = 50%)	706.29	0.49	1,452.85
Specificity (comparator) upper limit of 65% (base = 50%)	706.29	0.32	2,205.18

ENT, ear, nose and throat; MBS = Medicare Benefits Schedule.

### PICO Set 3

Due to the limited evidence available for PICO Set 3, a costing analysis was undertaken. The costs considered are presented in Table 17. The proposed fees for the new MBS items (\$284.19) are much lower than existing MBS items for Level 1 PSG (\$768.70 and \$692.50), owing to lower health practitioner staffing costs for out-of-laboratory sleep studies. The evaluation of the consequences of the out-of-laboratory studies in comparison to Level 1 PSG is limited by a lack of appropriate data.

**Table 17 Summary of the costs included in the economic evaluation for PICO Set 3**

Parameter	Value	Source
<b>Direct health technology costs</b>		
Level 3 CRP follow-up (monitoring) in a child diagnosed with OSA	284.19	DCAR
Level 3 CRP follow-up (monitoring) in an adolescent diagnosed with OSA	284.19	DCAR
Level 1 PSG in children for diagnosis or monitoring	768.70	MBS items 12210, 12215, October 2023
Level 1 PSG in adolescents for diagnosis or monitoring	692.50	MBS items 12213, 12217, October 2023
<b>Additional costs and/or cost offsets</b>		
General practitioner review and follow-up	41.20	MBS item 23, October 2023
Specialist physician review, initial	167.75	MBS item 110, October 2023
Specialist physician review, follow-up	83.95	MBS item 116, October 2023

CRP = cardiorespiratory polygraphy; MBS = Medicare Benefits Schedule; OSA = obstructive sleep apnoea; PSG = polysomnography.

## 14. Financial/budgetary impacts

A combined epidemiological and market-share approach was taken to estimate the use of paediatric out-of-laboratory sleep studies in Australia. Epidemiological information provides an estimate of the potential number of eligible patients, and market-share considerations explore the potential for currently listed MBS items for in-laboratory sleep studies (Level 1 PSG) to be replaced by the proposed out-of-laboratory MBS items.

For the paediatric population, the prevalent population with OSA in Australian children aged 3 to 11 years is estimated at 36,871 to 175,136<sup>26</sup>, and the symptomatic population based on habitual snoring is estimated at 322,620 to 467,031<sup>27</sup>. The utilisation of paediatric sleep study items on the MBS (7,115 claims in financial year 2017–2018) suggests a larger population of patients with SDB and OSA, and a much greater rate of surgical treatment for the condition, than the likely uptake of the proposed items.

### PICO Set 1

Assumptions based on data provided in the application form were used to estimate the rate of substitution in the market by the proposed Level 2 PSG services. The applicant estimated that 30% of wait-listed children and adolescents are likely to be eligible for Level 2 PSG. This value was applied to the pre-COVID-19 pandemic uptake of paediatric Level 1 PSG services and inflated by 10% to account for the expansion of uptake due to the introduction of out-of-laboratory sleep study services, anticipated based on analysis of adult services.

The financial implications to the MBS resulting from the proposed listing of out-of-laboratory Level 2 PSG services are summarised in Table 18. The net financial impact to the MBS is estimated to be a cost-saving of \$461,109 in 2023-24 rising to an additional cost to the MBS of \$306,739 in 2028–29 due to the greater growth rate of Level 2 compared to Level 1 services. If the growth rate is the same for Level 1 and Level 2 then the proposed service remains cost

<sup>26</sup> Based on a combination of Australian Bureau of Statistics population data and an estimate of proportion of children with OSA from Marcus et al. (2012).

<sup>27</sup> Based on a combination of Australian Bureau of Statistics population data and an estimate of proportion of children with OSA from Marcus et al. (2012).

saving. The costs are predominately attributable to use of the items for children rather than adolescents.

**Table 18 Net financial implications of PICO Set 1 out-of-laboratory Level 2 PSG to the MBS**

Parameter	2023—24	2024—25	2025—26	2026—27	2027—28	2028—29
<b>Estimated use and cost of the proposed services</b>						
Number of proposed Level 2 services (initial testing)	3,089	3,552	4,085	4,698	5,402	6,213
Growth in Level 2 services per year	15%	15%	15%	15%	15%	15%
Total cost to the MBS of proposed Level 2 services	\$1,067,964	\$1,228,159	\$1,412,382	\$1,624,240	\$1,867,876	\$2,148,057
<b>Change in use and cost of other services</b>						
Substitution of Level 1 services	-2,780	-2,919	-3,065	-3,218	-3,379	-3,548
Growth in Level 1 services per year	5%	5%	5%	5%	5%	5%
Total saving to the MBS of substituted Level 1 services	-\$1,680,219	-\$1,764,230	-\$1,852,442	-\$1,945,064	-\$2,042,317	-\$2,144,433
<b>Additional testing due to failed Level 2 tests</b>						
Number of first test failures for Level 2 PSG	308	355	409	469	540	621
Number of second test failures for Level 2 PSG	10	11	12	14	16	18
Total cost to the MBS for Level 2 PSG test failures	\$151,146	\$173,818	\$199,891	\$229,874	\$264,355	\$303,115
<b>Net financial impact to the MBS</b>	<b>-\$461,109</b>	<b>-\$362,254</b>	<b>-\$240,169</b>	<b>-\$90,950</b>	<b>\$89,914</b>	<b>\$306,739</b>

MBS = Medicare Benefits Schedule; PSG = polysomnography

<sup>a</sup> Level 1 PSG can be provided as either out-patient or in-patient services. The applicant advised that a greater proportion are in-patient in paediatrics than in adults; however, given the proportion is unknown, an 80% benefit has been applied as per MSAC guidelines (p214).

<sup>b</sup> It is assumed that half of Level 2 test failures repeat a Level 2 PSG and half have a Level 1 PSG, consistent with Section 3.

## PICO Set 2

The population for PICO Set 2 was estimated based on data provided in the application form that approximately 5% of patients on the waiting list for a sleep study would be suitable for a Level 3 CRP under PICO Set 2. This proportion was applied to the pre-COVID-19 pandemic uptake of paediatric Level 1 PSG services.

The financial implications to the MBS resulting from the proposed listing of out-of-laboratory Level 3 CRP services are summarised in Table 19. The net financial impact to the MBS is estimated to be \$134,102 in 2023—24, rising to \$269,728 in 2028—29. No Level 1 PSG studies are substituted as the comparator for this population is no sleep study. There is scope for the introduction of Level 3 CRP services to reduce the costs associated with adenotonsillectomy; however, this is not considered further in the financial analysis due to the very limited impact this is expected to have on the relevant health budgets. The annual rate of paediatric adenotonsillectomies for OSA in Australia is estimated at 33,376; this dwarfs the estimated eligible population for PICO Set 2 of whom fewer than half may avoid a tonsillectomy.

**Table 19 Net financial implications of PICO Set 2 diagnostic out-of-laboratory Level 3 CRP to the MBS**

Parameter	2023—24	2024—25	2025—26	2026—27	2027—28	2028—29
<b>Estimated use and cost of the proposed services</b>						
Number of proposed Level 3 services (initial testing)	515	592	681	783	900	1035
Growth in Level 3 services per year	15%	15%	15%	15%	15%	15%
Total cost to the MBS of proposed Level 3 services	\$124,356	\$143,009	\$164,461	\$189,130	\$217,499	\$250,124
<b>Additional testing due to failed Level 3 tests</b>						
Number of first repeat Level 3 CRP <sup>a</sup>	39	45	51	59	68	77
Number of second repeat Level 3 CRP <sup>a</sup>	0	0	0	0	0	0
Total cost to the MBS of Level 3 repeat testing	\$9,746	\$11,208	\$12,890	\$14,823	\$17,046	\$19,603
<b>Net financial impact to the MBS</b>	<b>\$134,102</b>	<b>\$154,218</b>	<b>\$177,350</b>	<b>\$203,953</b>	<b>\$234,546</b>	<b>\$269,728</b>

CRP=cardiorespiratory polygraphy; MBS = Medicare Benefits Schedule.

<sup>a</sup> It is assumed that half of Level 3 test failures repeat a Level 2 CRP and half have no further testing. The same assumption is applied following a second test failure, however a third test failure is assumed to not undergo further testing. The same test failure rate as used in the economic analysis has been applied.

### PICO Set 3

The size of the population for PICO Set 2 has been informed by data provided by the applicant estimating 1,045 children and adolescents required breathing support in Australia in 2019. This is consistent with Australian epidemiological data, which estimated 538 paediatric patients required non-invasive ventilation in Australia in 2007—08, a substantial increase from 156 in 1997—98 (Edwards & Nixon 2013<sup>28</sup>). Half of these were estimated to be suitable for out-of-laboratory monitoring.

The financial implications to the MBS resulting from the proposed listing of out-of-laboratory Level 3 CRP services for monitoring are summarised in Table 20. The net financial impact to the MBS is a cost saving due to the substitution of Level 3 for Level 1 monitoring studies; estimated to be \$364,624 in 2023—24, rising to a saving of \$465,362 in financial year 2028—29.

The main source of uncertainty is the number of monitoring tests that would be undertaken each year in the intervention and comparator scenarios and whether these would differ. If currently half of recommended monitoring visits are undertaken but the introduction of Level 3 CRP monitoring results in all patients undergoing recommended monitoring, then the substitution rate would be two Level 3 CRPs for every one Level 1 PSG, thereby reducing the cost saving to \$56,096 in 2023—24 to \$71,594 in 2028—29.

<sup>28</sup> Edwards EA, and Nixon GM (2013) 'Paediatric home ventilatory support: changing milieu, proactive solutions. Australasian Paediatric Respiratory Group Working Party on Home Ventilation.', *J Paediatr Child Health*, 49(1): 13-18, doi:<https://doi.org/10.1111/jpc.12040>.

**Table 20 Net financial implications of PICO Set 3 monitoring out-of-laboratory Level 3 CRP to the MBS**

Parameter	2023—24	2024—25	2025—26	2026—27	2027—28	2028—29
<b>Estimated use and cost of the proposed services</b>						
Estimated eligible population for Level 3 monitoring services	523	549	576	605	635	667
Growth in Level 3 monitoring services per year	5%	5%	5%	5%	5%	5%
Number of proposed Level 3 monitoring services (2 per year)	1045	1097	1152	1210	1270	1334
Total cost to the MBS of proposed Level 3 monitoring services	\$252,432	\$265,053	\$278,306	\$292,221	\$306,832	\$322,174
<b>Change in use and cost of other services</b>						
Substitution of Level 1 monitoring services	100%	100%	100%	100%	100%	100%
Number of proposed Level 1 monitoring services substituted	1045	1098	1153	1210	1270	1334
Total saving to the MBS of substituted Level 1 monitoring services	-\$617,055	-\$647,908	-\$680,304	-\$714,319	-\$750,035	-\$787,536
<b>Net financial impact to the MBS</b>	<b>-\$364,624</b>	<b>-\$382,855</b>	<b>-\$401,998</b>	<b>-\$422,097</b>	<b>-\$443,202</b>	<b>-\$465,362</b>

FY = financial year; MBS = Medicare Benefits Schedule

<sup>a</sup> Level 1 PSG can be provided as either out-patient or in-patient services. The applicant advised that a greater proportion are in-patients in paediatric populations than in adult populations; however, given the proportion is unknown, an 80% benefit has been applied as per MSAC guidelines (p214).

### Combined Financial Impact for PICO Set 1, 2 & 3

Table 21 reports the total costs to the MBS for all three populations. There was a very large change between years 1 (net savings of \$691,631) and 6 (net costs of \$111,105).

**Table 21 Net financial implications of PICO Sets 1-3 to the MBS**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
PICO 1	-\$461,109	-\$362,254	-\$240,169	-\$90,950	\$89,914	\$306,739
PICO 2	\$134,102	\$154,218	\$177,350	\$203,953	\$234,546	\$269,728
PICO 3	-\$364,624	-\$382,855	-\$401,996	-\$422,097	-\$443,202	-\$465,362
<b>TOTAL</b>	<b>-\$691,631</b>	<b>-\$590,891</b>	<b>-\$464,815</b>	<b>-\$309,094</b>	<b>-\$118,742</b>	<b>\$111,105</b>

## 15. Other relevant information

### NATA Accreditation of paediatric sleep service providers

The applicant has requested that service providers for the requested items be limited to those sleep laboratories with NATA accreditation according to Table 22.

**Table 22 NATA accreditation requirements requested for the service provided**

Responsibility	Studies in children aged 3 to >12 years	Studies in children aged 12 to <18 years
Study supervision, including determination of whether CO <sub>2</sub> recording is required	A qualified paediatric sleep medicine practitioner listed on the staff of a <i>paediatric sleep laboratory</i> accredited under the NATA/ASA Sleep Disorders Service Accreditation Program	A qualified paediatric or adult sleep medicine practitioner who is listed on the staff list of a <i>paediatric or adult sleep laboratory</i> accredited under the NATA/ASA Sleep Disorders Service Accreditation Program <i>for this age group</i>
Interpretation and preparation of the report including review of the raw polygraphic data		

ASA = Australasian Sleep Association; NATA = National Association of Testing Authorities. Source: Application form for MSAC application 1712 (February 2022)

Recording of carbon dioxide (capnography) is relevant to children with underlying conditions putting them at higher risk of central apnoea, or otherwise more complex than suspected obstructive sleep apnoea alone.

A requirement for paediatric sleep studies to be delivered by a NATA accredited laboratory (for both age groups) would help manage a range of clinical, quality and compliance issues summarised in Table 23.

**Table 23 Issues addressed by a requirement for NATA accreditation of paediatric sleep laboratories**

Area	Rationale/comment
Clinical care	Children receive appropriate specialist clinical assessment and care in addition to the sleep study itself. Children are assessed by a specialist to determine whether capnography should be included in the sleep study and whether an out-of-laboratory study is appropriate.
Quality standards	Only laboratories with appropriately trained staff offer these services. Accreditation to cover conduct of sleep studies in the home environment. Conduct of regular audits to ensure the more complex scoring and interpretation of study polygraphs and other data required for children is being performed to an appropriate standard. Quality program oversight of sleep study ordering and conduct.
Compliance and item use outside the intended population	The pattern of utilisation adopted by certain sleep disorder businesses for adult out-of-laboratory studies is not repeated for children.

NATA = National Association of Testing Authorities.  
Source: compiled for this assessment report.

If NATA accreditation is recommended, 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 MBS Schedule explanatory notes IN.0.4 and PN.8.2, respectively). This could also simplify the item descriptor text as restrictions or clinical criteria could be managed within the scope of the audit program (where appropriate).

The main benefits for such a restriction would be in ensuring that sleep study data are interpreted by a technician with appropriate training. Additionally, quality assurance and audit processes would ensure the studies are conducted to an appropriate standard. Although NATA accreditation may not fully address appropriate patient selection for out-of-laboratory sleep



studies at an individual clinician level, it would assist in ensuring that those working at the sleep laboratory adhere to good practice regarding patient selection.

### **Evidence for out-of-laboratory sleep studies in adolescents**

Adenotonsillar hypertrophy as the underlying cause of OSA is predominantly a condition of pre-school and primary school aged children. This was reflected in the age groups studied in paediatric sleep studies. Adolescents, in comparison, share more characteristics with adults in their OSA features than with children under 12 years (due to higher incidence of obesity and emergence of adult features of the upper respiratory tract) (Marcus et al. 2017). Adolescents referred for sleep studies are also more likely to have chronic or congenital illnesses requiring long-term management, such as muscular dystrophy or obesity.

There is correspondingly much less evidence for the proposed items in adolescents, which was acknowledged by both the applicant and the PASC in the ratified PICO confirmation. Support for use of the proposed sleep studies in adolescents has relied on extrapolation of conclusions made from studies primarily in children under 12 years old. An alternative argument could be made for considering sleep studies for adolescents as an extension of the adult sleep study items, but this was out of scope for this assessment.

### **Sleep studies in the context of first line surgery for OSA**

Surgery is the first line treatment for children and adolescents with OSA, comprising tonsillectomy, adenoidectomy, or tonsillectomy with adenoidectomy (referred to herein as adenotonsillectomy) (Nixon & Davey, 2015<sup>29</sup>; McGahan & Scott, 2015<sup>30</sup>; ACSQHC 2021<sup>31</sup>). As part of the assessment, a total number was estimated of adenotonsillectomy surgeries in Australia due to OSA of 33,376 per annum. This provides context for the number of paediatric sleep studies undertaken to investigate treatments for OSA.

## **16. Key issues from ESC to MSAC**

### **Main issues for MSAC consideration**

#### **Clinical issues:**

- The claim that out-of-laboratory sleep studies would decrease the number of adenotonsillectomies being performed is not supported by evidence.
- The current clinical management algorithm is unclear in terms of when a sleep study is required/beneficial for deciding management, and what the drivers are for sleep study waiting lists. ESC suggested seeking expert advice to clarify when sleep studies are required to make clinical management decisions, and understand what are the most common indications for a sleep study for children on waiting lists. Data on the following may be useful for MSAC decision-making:

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<sup>29</sup> Nixon GM, and Davey M (2015) 'Sleep apnoea in the child', *Aust Fam Physician*, 44(6): 352-355, <https://www.ncbi.nlm.nih.gov/pubmed/26209982>.

<sup>30</sup> McGahan L, Scott A (2015). 'Tonsillectomy, Adenoidectomy and Adenotonsillectomy for Obstructive Sleep Apnoea: Review of Clinical Evidence and Guidelines', Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S). The Royal Australasian College of Surgeons. Report produced for the Victorian Government Department of Health, Melbourne.

<sup>31</sup> ACSQHC (Australian Commission on Safety and Quality in Health Care; Australian Institute of Health and Welfare) (April 2021) *The Fourth Australian Atlas of Healthcare Variation*, last accessed 13 December 2023.

- how many children with sleep disordered breathing (SDB) are managed with continuous positive airway pressure/bilevel positive airway pressure (CPAP/BiPAP) (sleep study likely needed)
- how many children considered for adenotonsillectomy are at high risk of anaesthesia, surgery or post operative complications (sleep study recommended)
- how many children on current waiting lists for Level 1 studies have no high-risk or complicating factors (aged  $\geq 3$  years, low risk of hypoventilation, no other potential sleep disorders, no severe behavioural issues) and are therefore representative of the proposed population for PICO set 1 and would be eligible for Level 2 polysomnography (PSG).

**Economic issues:**

- For population 1 (low-risk uncomplicated patients), a cost-minimisation analysis reporting favourable cost savings may not be acceptable given the lower accuracy of the intervention (Level 2 PSG) compared to Level 1 studies.
- There are uncertainties associated with the PICO set 2 economic evaluation. The results in favour of a Level 3 cardiorespiratory polygraphy (CRP) test may not be reasonable given no evidence was provided on test accuracy or effectiveness and whether adenotonsillectomies will be avoided or unaffected by use of the test. The cost-effectiveness was also based on very sparse data (n = 34 from a trial excluding failures/losses).
- The cost-effectiveness analysis for PICO Set 2 used the cost of tonsillectomy as a willingness-to-pay threshold (i.e. assumed cost-effective if the incremental cost per tonsillectomy avoided was less than the cost of a tonsillectomy). ESC acknowledged the data limitations but emphasised neither this specific approach to cost effectiveness analysis nor cost effectiveness analysis in general is the preferred method for MSAC decision-making, which is to use a cost-utility analysis when the clinical claim is of superiority.

**Financial issues:**

- Risk for use outside the intended population for populations 1 and 3 which could result in larger utilisation than estimated in the financial analysis. The utilisation may also be higher if the assumed replacement of Level 1 sleep studies does not occur and services are additional or grow at a faster rate than predicted.

**Other relevant information:**

- It appears that the decisions to perform some adenotonsillectomies in Australia may not be supported by evidence. ESC suggested that it may be appropriate to refer a review of MBS item 41789 to the Medicare Benefits Schedule Review Advisory Committee (MRAC).
- Out-of-pocket costs after taking account of the costs of equipment, delivery set up and return of equipment may be significant and may offset the claims of improved access and convenience (compared to no sleep studies or Level 1 in-hospital studies incurring travel costs).
- The proposed MBS listing of out of laboratory sleep studies may have the following unintended consequences: (i) There is a risk that sleep laboratory sites may not maintain current skills in accommodating children with disability or sensory support needs; (ii) There is a risk that access to current State based schemes that provide transport subsidies to remote patients (such as NSW's Isolated Patient Travel and Accommodation Assistance Scheme) may be compromised if patients and their carers preferred to have a sleep study at a sleep laboratory, but home-based options became available..

**ESC discussion**

ESC noted that this application from the Australasian Sleep Association was for the Medicare Benefits Schedule (MBS) listing of out-of-laboratory sleep studies (Levels 2 and 3) for the

investigation of sleep disordered breathing (SDB) in children and adolescents (ages 3 to <18 years).

ESC recalled that, in 2010, MSAC supported funding Level 2 sleep studies for obstructive sleep apnoea (OSA) in adults (application 1130). At the time, MSAC did not support Level 3 and 4 sleep studies, nor any unattended paediatric sleep studies. ESC recalled that MSAC acknowledged there was a lack of comparative evidence and sparse linked evidence to indicate the effectiveness of unattended sleep studies for a paediatric population, relative to Level 1 sleep studies ([public summary document, p.4](#)). ESC considered the evidence remains sparse for this application 1712; although diagnostic accuracy studies were identified for both Level 2 polysomnography (PSG) and Level 3 cardiorespiratory polygraphy (CRP), these studies are small, and it is unlikely that larger studies will be available for a paediatric indication. ESC noted that additional sources of supporting evidence were used to address gaps in evidence for this application.

ESC noted the six proposed MBS items, differing in cost depending on patient age and purpose (diagnosis versus monitoring). All items had a maximum claiming frequency of three in one year of any combination of MBS items proposed. ESC noted that the department commissioned assessment report (DCAR) did not provide justification or comparison of the proposed MBS fees, so ESC could not comment on their appropriateness though ESC also noted that the level of fees proposed was consistent with the exclusion of a respiratory scientist in continuous attendance.

ESC noted that the Department questioned whether two new Level 3 MBS items, i.e. both investigation and monitoring of sleep items for children and adolescents needed to be created for PICO sets 2 and 3. ESC noted that having separate items would better facilitate ease of monitoring use of each of these specified services.

ESC considered it inappropriate to include costs for telehealth consultations in the MBS items, as these costs may differ for different patients and proposed that instead these telehealth services could be claimed separately. ESC also noted potential telehealth accessibility issues for rural families, such as poor internet access, although it considered that this should not preclude telehealth from being offered to rural patients.

However, the Department noted that there may be significant challenges in implementing telehealth components of this service separate from the proposed item numbers, as MBS telehealth items can currently only be claimed by Medicare eligible practitioners, and require specific circumstances to be met. Sleep technicians are not eligible to claim Medicare items, therefore claiming a separate MBS item for telehealth services delivered solely by a technician is unlikely to be possible. The department advised the Medical Benefits Schedule Review Advisory Committee (MRAC) is currently finalising the Telehealth post-implementation review and that the outcomes of this review will impact any future telehealth items.

ESC noted the Department queried whether there was sufficient justification to require the patient to be referred to a paediatric sleep physician given concerns with current access to paediatric sleep physicians. ESC also considered whether access for children who live in Tasmania and the Northern Territory where there are no permanent sleep specialists may be another limiting factor but noted that these patients were typically referred to specialists in larger mainland states. ESC queried whether in these circumstances, access to home tests with telehealth support from larger sites in mainland states could be possible. However, overall ESC considered that access issues needed to be balanced against the risk for use in other unintended populations if referrals were made inappropriately. ESC considered that there may be possible benefit to widening the SDB population eligible for the service so that clinical decision making could be better informed by sleep study results. However, the evidence for this potential benefit was not presented in the current application, and would need to be formally assessed.

ESC noted that most stakeholders requested that any laboratories conducting out-of-laboratory sleep studies be quality controlled through National Association of Testing Authorities (NATA) accreditation. ESC noted that this was not a current requirement for MBS sleep study items, and there appears to be a small number of paediatric NATA-accredited sleep laboratories within Australia. ESC was uncertain if this requirement was necessary, but noted that, if implemented, this requirement may inadvertently create a patient access barrier when an accredited sleep laboratory is not accessible or available to a patient.

ESC noted and welcomed consultation input from 4 professional organisations and 1 consumer organisation, the Sleep Health Foundation which noted that they only had a week to consider a response, and that they would, if given time, be happy to organise a group of consumers (parents of children with sleeping issues) and present a formalised summary of their main concerns and what the challenges have been in accessing sleep studies. ESC noted support from several organisations that stated there is a clinical need for such a service to: reduce lengthy waiting times for sleep studies; improve access for children in rural and remote regions; and improve access to treatment, including adenotonsillectomy. The Thoracic Society of Australia and New Zealand considered that such a service may decrease unnecessary adenotonsillectomies.

ESC considered that the proposed clinical need for the intervention needed further interrogation. In particular, assuming there is an unmet clinical need for the proposed service, the consultation feedback suggested the unmet clinical need could be for one or both of the following:

- To reduce overservicing of adenotonsillectomies
  - o However, ESC questioned whether many parents of children offered surgery as a possible management option for their child's symptoms or medical history, who were then found to have normal/mild OSA test findings, would actually choose watchful waiting and forgo surgery. ESC also questioned whether parents of children at higher risk from anaesthesia or surgery and with mild OSA test findings would actually choose watchful waiting. No evidence was provided in the DCAR to support the case that either of these possibilities would actually occur.
- To reduce wait times for those most in need of a Level 1 study
  - o ESC questioned whether low-acuity patients were the main driver for long wait times (which ESC discussed further below).

ESC noted that the rate of tonsillectomies is higher in Australia than in similar countries such as the UK. The [Fourth Australian Atlas of Healthcare Variation 2021](#) stated that “high or low rates of tonsillectomy in some areas may be related to clinical practice that is not supported by evidence ... There is no current Australian evidence-based guideline for the use of tonsillectomy in managing recurrent throat infections and OSA in children”. The Atlas went on to state that while the gold standard for diagnosing OSA before tonsillectomy is an overnight inpatient sleep study, differences in diagnosing OSA and the referral process for sleep studies may contribute to variation, and that children in rural and remote areas may be disadvantaged in accessing timely sleep studies. ESC considered that based on the findings from the Atlas of Variation that the decision to undertake some adenotonsillectomy surgeries in Australia may not be supported by evidence. ESC suggested that it may be appropriate to refer a review of MBS item 41789 to the MBS Review Advisory Committee (MRAC).

ESC also noted evidence from Hazkani et al. (2023) that adenotonsillectomies improve “parental perception of the child’s QoL [quality of life] and burden of sleep-related symptoms”<sup>32</sup>. ESC noted evidence from Redline et al. (2023) that in children with mild sleep-disordered breathing, adenotonsillectomy resulted in no statistically significant differences in changes in executive

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<sup>32</sup> Hazkani et al. (2023). [Adenotonsillectomy or watchful waiting for pediatric sleep-disordered breathing](#), *JAMA*, 330(21):2057–8.

function or attention but led to improved secondary outcomes including parental reported symptoms and behaviour, and blood pressure<sup>33</sup>.

ESC noted the three populations in the DCAR:

1. children aged 3 to <12 years and adolescents aged 12 to <18 years with a high probability for symptomatic moderate to severe OSA (intervention: diagnostic out-of-laboratory Level 2 PSG) – considered low-risk patients
2. children aged 3 to <12 years and adolescents aged 12 to <18 years with a high probability for symptomatic moderate to severe OSA (intervention: diagnostic out-of-laboratory Level 3 CRP) – patients that cannot tolerate a Level 1 sleep study
3. children aged 3 to <12 years and adolescents aged 12 to <18 years who are stable on continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP) respiratory support (intervention: diagnostic out-of-laboratory Level 3 CRP for treatment monitoring).

ESC noted the clinical management algorithms for the populations.

For populations 1 and 2, ESC noted several issues:

- Although the population eligible for Level 2 PSG are defined as children with a high probability of OSA, in reality it is possible that use outside the intended population may occur and patients across the full spectrum of sleep disordered breathing (from mild sleep disordered breathing to OSA) may receive a Level 2 PSG.
- It is unclear when the results of a sleep study (confirming or ruling out a diagnosis of OSA) is required (i.e. directly/solely informs a change in patient management) or beneficial (i.e. one of a number of factors that helps inform patient management) for deciding management options. For example, it is clear that a sleep study is required for CPAP/BiPAP initiation and sometimes monitoring but less clear how much importance is placed on a sleep study result to determine other management options, such as surgery. That is, it appears other clinical factors may result in a decision being made to progress to adenotonsillectomy, which may occur even if the sleep study is negative for OSA.
- Children who cannot tolerate an in-laboratory sleep study (population 2) may be difficult to define, thus there is potential for use outside the intended population.

For population 3, ESC queried whether laboratory-based sleep studies were required for patients who are clinically stable, and whether the proposed intervention for monitoring purposes would occur unnecessarily in clinical practice for clinically stable patients (i.e. potential for overservicing).

ESC considered that in order to better clarify the current and proposed clinical algorithms in the DCAR and address the questions relating to clinical need outlined previously, further expert advice should be sought on when sleep studies are needed to decide management, and the most common indications for needing a sleep study for children on waiting lists for sleep studies. This would also require additional data on the following possible components of paediatric sleep studies utilisation:

- how many children with SDB are currently managed with CPAP/BiPAP (sleep studies are likely to be needed to initiate non-invasive ventilation, and for monitoring if not clinically stable)

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<sup>33</sup> Redline et al. (2023). Adenotonsillectomy for snoring and mild sleep apnea in children: a randomized clinical trial. *JAMA*, 330(21):2084-2095

- how many children considered for tonsillectomies and adenoidectomies are at high risk of anaesthesia, surgery or post operative complications (sleep studies are recommended to determine likely benefits of surgery, to weigh up against potential risks)
- How many children on current waiting lists for Level 1 study have no high risk or complicating factors (aged  $\geq 3$  years, low risk of hypoventilation, no other potential sleep disorders, no severe behavioural issues) (current proposed clinical algorithm for PICO set 1)

ESC noted the application's clinical claims:

- Provision of out-of-laboratory sleep studies will
  - improve access to sleep monitoring services
  - improve consumer satisfaction
  - reduce wait times for Level 1 PSG
  - reduce time to diagnosis and treatment of SDB.
- PICO set 1: Level 2 PSG is non-inferior to Level 1 PSG. ESC noted that while Level 2 PSG is proposed to be a replacement test for Level 1 PSG, there is also the potential for it to be an additional test for children with SDB who would not have had an in-laboratory sleep study.
- PICO set 2: Level 3 CRP is superior to no test (additional test).
- PICO set 3: Level 3 CRP is non-inferior to Level 1 PSG (replacement monitoring test).

ESC noted the modest evidence base for the clinical effectiveness claims, and the lack of evidence for safety of the intervention. No comparative studies met the inclusion criteria and reported safety outcomes. One included study, Griffiths et al. (2022)<sup>34</sup> – an Australian single-arm, single-centre, retrospective audit of Level 2 PSG studies (diagnostic) – reported no adverse events during the study period. ESC acknowledged that out of laboratory sleep tests may reduce the risk of nosocomial respiratory infections compared to in-laboratory settings, especially for population 3, who have a high rate of complex comorbidities (although no evidence was submitted to support this in the DCAR).

ESC noted that patient and family choice about the location of their care is important and that while home-based sleep testing has the potential to improve access for families whose children have neurodevelopmental disabilities and neurotypes that make hospital visits challenging or inaccessible this may not be sufficiently captured in the evidence due to lack of representation from these groups in relevant studies. Therefore, ESC recommended that the Department's Consumer Evidence and Engagement Unit could seek input from consumer groups who represent people with autism spectrum disorder, Down syndrome and other neurodevelopmental disabilities as children with these conditions may not be adequately represented in the research but may have limited access to sleep studies.

For clinical effectiveness, the studies supporting the claim comprised systematic reviews, case series and single-arm studies. Evidence was not identified for all populations.

ESC noted that the sensitivity and specificity of Level 2 PSG was comparable to Level 1 PSG, and there were no differences in test failures for population 1; however, ESC considered the GRADE certainty of evidence for these to be uncertain.

ESC noted that there was no evidence for change in management for population 1. The applicant indicated that clinical management decisions are not made based on the PSG findings alone and incorporate symptoms, physical findings (such as tonsil and adenoid size), and patient and

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<sup>34</sup> Griffiths A, Mukushi A, and Adams AM (2022) 'Telehealth-supported level 2 pediatric home polysomnography', *Journal of Clinical Sleep Medicine*, 18(7): 1815-1821, doi:<https://doi.org/10.5664/jcsm.9982>.

caregiver preferences. This is also suggested by feedback from ASOHNS that most children having surgery are diagnosed clinically based on their history and examination. Therefore, ESC considered it highly uncertain that sleep study findings will overturn operative management decisions based on these other factors. ESC also noted potential financial incentives for ENT surgeons in private practice to perform adenotonsillectomies regardless of sleep study findings. ESC also considered it reasonable to assume that a diagnosis of OSA (or otherwise) will lead to the same treatment decisions regardless of how it is reached. The DCAR noted that a change in management is not required for truncated assessment framework, which ESC considered to be true if the proposed test is replacing an existing test (i.e. Level 1 sleep studies). However, ESC considered that if a test is proposed in addition to current standard of care (i.e. used in populations who currently have no sleep study), which ESC considered could be the case for Level 2 PSG (as noted earlier), then evidence on change in management would be needed.

For population 2, ESC noted that the included studies for diagnostic accuracy had high risk of bias. Additionally, ESC was concerned about the applicability of the studies given that none of the included studies were undertaken on populations intolerant of head leads. ESC noted that the incremental diagnostic value is likely to be minimal (or zero) in the study populations. No evidence on incremental value was identified for the actual target population. ESC also considered that there is uncertainty in applying the evidence to the intended use population, particularly with respect to failure rates. Higher failure rates are likely, with the rate of 26% failure at first attempt and 19% at second attempt for the cohort with Down syndrome (Kingshott et al. 2019).<sup>35</sup> Thus, ESC concluded that the claim of superiority for test accuracy is not supported by evidence.

ESC noted that no studies met inclusion criteria for change in management for population 2. The DCAR suggested that Kissow Lildal et al. (2023)<sup>36</sup> provided data on theoretical management changes. However, since 34 patients had an adenotonsillectomy, including 19 without moderate–severe OSA and 5 without any OSA based on a Level 1 PSG, ESC considered that most patients would proceed with a planned tonsillectomy regardless of the sleep study findings. Thus, ESC concluded that the claim of superiority for clinical utility is not supported by evidence.

ESC noted the systematic reviews on health outcomes for population 2, which suggested that adenotonsillectomies improve quality of life and similar findings from a more recent 2023 study that this also holds for those with milder SDB. However, ESC again considered that there was no evidence to suggest that a sleep study will overturn any previous recommendations for surgery and therefore, it was unclear what the relevance of these findings are to those undertaking out of laboratory sleep studies. ESC also noted the [Fourth Australian Atlas of Healthcare Variation 2021's](#) findings that most information provided to parents/carers about adenotonsillectomies highlighted the positive outcomes of surgery and downplayed risks.

For population 3, ESC noted that no studies met the inclusion criteria for test accuracy, so it was inferred from the studies that informed population 2. However, it is unknown if these results would translate to children on respiratory support. ESC also noted that there was insufficient evidence to support a change in management or improvements in health outcomes in population 3. ESC considered a possible benefit of the intervention in this population was avoiding a hospital stay for patients with complex, ongoing medical conditions and their families.

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<sup>35</sup> Kingshott RN, Gahleitner F, Elphick HE, Gringras P, Farquhar M, Pickering RM, Martin J, Reynolds J et al. (2019) 'Cardiorespiratory sleep studies at home: Experience in research and clinical cohorts', *Archives of Disease in Childhood*, 104(5): 476-481, doi:<https://doi.org/10.1136/archdischild-2018-315676>.

<sup>36</sup> Kissow Lildal T, Boudewyns A, Kamperis K, Rittig S, Bertelsen JB, Otto M, Nørregaard O, and Ovesen T (2023) 'Validity of in-lab and home respiratory polygraphy for detecting obstructive sleep apnea in children', *Sleep Medicine*, 103: 195-203, doi:<https://doi.org/10.1016/j.sleep.2023.01.016>.

Overall, ESC concluded that:

- For PICO set 1 the claim of non-inferior test accuracy was uncertain and testing success was likely inferior though offset by the convenience of home-based testing. The overall claim of non-inferior effectiveness was uncertain and assumed that the test would be a replacement for Level 1 studies rather than an additional test.
- For PICO set 2, there was no evidence on test accuracy, clinical utility, or effectiveness, testing success is unknown and thus it was highly uncertain that the test could improve patient selection for adenotonsillectomy and lead to safer outcomes.
- For PICO set 3 there is likely inferior accuracy, and inferior change in management, but this may be offset by likely increased acceptability to user population.

ESC noted that three economic analyses were conducted: one for each PICO set.

For PICO set 1, the DCAR presented a cost-minimisation analysis. ESC noted that the intervention was lower cost, albeit lower accuracy, than the comparator, but resulted in cost savings of \$645.29 per accurate diagnosis. The main driver of this was the intervention's sensitivity – at the lower limit of sensitivity, the intervention was not cost saving and resulted in a net cost of \$379.87, but it was cost saving for all other scenarios in the sensitivity analysis. However, ESC queried whether the use of cost minimisation to find cost savings (relative to the comparator) was acceptable given the lower accuracy of the test since this ignored possible adverse outcomes from the lower test accuracy which was not taken into account in this analysis.

For PICO set 2, the DCAR presented a cost-effectiveness analysis based on a willingness-to-pay threshold where this threshold was set at the cost of performing a tonsillectomy at \$2721.41. As the cost per tonsillectomy avoided in the base case was \$1,751.65 and this was lower than the cost of performing a tonsillectomy, this result was reported by the DCAR as cost effective. However, ESC considered that the claim of tonsillectomies avoided was not supported by the evidence for the reasons discussed previously i.e. it was highly uncertain based on the evidence that sleep study findings would overturn operative management decisions based on a range of other considerations. ESC considered that other key limitations of the approach to the economic evaluation are the lack of utility data, and that most of the clinical inputs were based on non-randomised data or expert opinion. The evaluation was based on very sparse data (n = 34 from trial, excluding failures/losses). In addition, potential downstream benefits of avoiding tonsillectomies (such as reduced rates of complications) could not be quantified and were excluded. However, a range of sensitivity analyses suggest that the conclusion of cost-effectiveness is robust to substantial parameter uncertainty.

ESC queried the appropriateness of using a willingness-to-pay threshold for PICO set 2 (for avoidance of surgery). ESC noted that a similar approach was used where there was no alternative method to calculate quality-adjusted life years gained or life years lost but a benchmark for understanding the meaning and implications of an estimated cost was needed. However, ESC noted that in previous applications MSAC and its sub-committees had recognised a preference for economic evaluations to be presented as cost utility analyses (CUAs) (whenever the data allowed) rather than cost effectiveness analyses (CEAs), as stated in the MSAC Guidelines and recommended that this continue to be the stated preference.

The DCAR used a cost-analysis approach for PICO set 3. ESC noted that this was not a comprehensive cost analysis as it only included consideration of MBS fees ESC noted that the proposed fee of \$284.19 is lower than any of the comparator costs, mainly due to the lower health practitioner costs associated with out of laboratory sleep studies.

ESC noted that the financial impact for PICO set 1 is cost saving in years 1–4 to cost positive in years 5 and 6, because of the greater growth rate of Level 2 services compared with Level 1. ESC noted that population 1 (uncomplicated patients) is the largest population of the three sets. ESC



noted that there were no savings for PICO set 2 because the intervention was not replacing an existing service. ESC noted that there was an expected cost saving to the MBS for PICO set 3 because Level 3 CRP would replace Level 1 monitoring studies. ESC noted the total costs to the MBS for all three populations, and that there was a very large change between years 1 (net savings of \$691,631) and year 6 (net costs of \$111,105)(Table 21).

However, ESC noted that the estimated uptake populations for PICO sets 1 and 2 are significantly smaller than the eligible populations, so higher uptake is possible. ESC noted that there is also the potential for use of the proposed items outside the intended populations 1 and 3 that could result in larger utilisation than estimated here. The utilisation may also be higher if the assumed replacement of Level 1 sleep studies does not occur and services are additional or grow at a faster rate than predicted.

Based on current data on patient out-of-pocket costs for items 12210<sup>37</sup> and 12213<sup>38</sup> ESC considered that out-of-pocket costs may be substantial relative to average fees charged. These out-of-pocket costs for the proposed services may be proportionally higher for patients who live further away from accredited sleep laboratories if the cost of equipment delivery, setup and return of the equipment is billed separately to the patient. ESC therefore noted possible access issues if the proposed service was listed, such as high out-of-pocket costs, which would need to be addressed.

ESC noted some additional access issues that may be raised with the introduction of these proposed items:

- whether new home testing options may have unintended consequences including sleep laboratory sites not maintaining current skills in accommodating children with disability or sensory support needs, and
- whether introducing home-based sleep studies might have impacts on people's access to current State based schemes that provide transport subsidies to remote patients (such as NSW's Isolated Patient Travel and Accommodation Assistance Scheme) if their preference was to have a sleep study at a sleep laboratory, but home-based options became available.

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<sup>37</sup> Overnight paediatric investigations by a paediatric sleep medicine practitioner for patients less than 12 years of age.

<sup>38</sup> Overnight paediatric investigations by a paediatric sleep medicine practitioner for patients between 12 and under 18 years of age.

## **17. Applicant comments on MSAC's Public Summary Document**

The Australasian Sleep Association is disappointed that out of laboratory sleep studies in children and adolescents have not been recommended for public funding. The application was initiated and submitted by expert clinicians in paediatric sleep medicine who were seriously concerned about significant numbers of children and adolescents currently remaining undiagnosed and untreated for obstructive sleep apnoea. Future health utilisation costs and adverse health and wellbeing outcomes for these children are significant, and strong support was expressed by all expert and consumer organisations who submitted comments on the application. There is repeated comparison in this public summary document to adults with sleep disordered breathing. The clinical and health system circumstances for these populations are different and these comparisons are inappropriate. Furthermore, the level of evidence required for paediatric applications can never match that for adult services, given the limited international research funding for paediatric services such as those in sleep medicine. This is acknowledged internationally and Australia is one of the few developed health systems that does not have access to funded home-based sleep studies in children. The applicant disagrees with a number of the equity and accessibility concerns that have been raised and reiterates that the application was designed to increase access to diagnostic testing and to decrease wait list times, especially for underserved children such as those with disabilities and those in rural and regional areas.

## **18. Further information on MSAC**

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)