Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1712.1 – Level 2 sleep studies for the diagnosis and management of sleep disordered breathing in children and adolescents

Applicant: **Australasian Sleep Association**

Date of MSAC consideration **31 July 2025**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application

A re-application requesting Medicare Benefits Schedule (MBS) listing of Level 2 polysomnography (PSG) out-of-laboratory sleep studies for the diagnosis and management of sleep disordered breathing (SDB) in children and adolescents was received from the Australasian Sleep Association by the Department of Health, Disability and Ageing.

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 supported the creation of new MBS items for Level 2 PSG out-of-laboratory sleep studies for the diagnosis and management of SBD in children (ages 3-11 years, inclusive) and adolescents (ages 12-17 years, inclusive). MSAC considered the updated waitlist data demonstrated a clear clinical need for Level 2 PSG to increase testing capacity for children and adolescents. MSAC considered MBS listing of Level 2 PSG would only partially address wait times for sleep studies due to the low number of referring paediatric sleep physicians, although noted a recent increase, with an expectation that this number would increase further given those in training. MSAC considered referral by a sleep physician is important to ensure patients are appropriately referred to either Level 1 or 2 studies.

MSAC recalled it had previously considered Level 2 PSG non-inferior in test accuracy, effectiveness and safety compared to Level 1 PSG in the proposed population. MSAC considered test success may be lower with Level 2 PSG but considered this was acceptable to improve access to sleep studies. MSAC noted that Level 2 PSGs are currently publicly funded under the MBS for adult patients aged 18 years or older. MSAC noted the revised economic evaluation found that Level 2 PSG was cost-saving relative to Level 1 PSG. The revised financial analysis indicated MBS funding of Level 2 PSG would be cost saving in the first year with a modest increase in subsequent years as utilisation grows, predominantly in children (ages 3-11, inclusive). However, MSAC considered the proposed MBS items (including the fee) required amendments to ensure equitable access. MSAC supported two MBS items, one for children and another for adolescents, with fees of $466.30 and $433.30, respectively, and access to telehealth support for all patients. MSAC did not support any separate MBS item(s) with alternative fees for patients from rural or remote areas, noting the service provided is the same regardless of location. MSAC advised the utilisation of the new items should be reviewed 2 years after implementation.

Consumer summary

This re-application from the Australasian Sleep Association requested Medicare Benefits Schedule (MBS) listing of Level 2 polysomnography (PSG) out-of-laboratory sleep studies for the diagnosis and management of sleep disordered breathing in children (ages 3-11 years) and adolescents (ages 12-17 years). This is the third time MSAC has considered public funding of Level 2 PSG for children and adolescents.

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

Obstructive sleep apnoea can be diagnosed with a sleep study. The traditional and most complete type of sleep study is a Level 1 PSG, which is done as an overnight stay in a hospital or sleep clinic with a sleep technician or sleep nurse monitoring the whole study. However, there are several reasons why some patients cannot stay in a hospital or clinic overnight, including that they live too far away (such as in a rural or remote area). Level 2 PSG out-of-laboratory sleep studies can be done at home or at another location that is not a sleep laboratory. Level 2 PSGs record fewer parameters than a Level 1 PSG but overall collect similar information and can be used to diagnose obstructive sleep apnoea. A sleep technician helps parents or carers (either in person or via telehealth) to set up the equipment at home, including correctly sticking-on the electrodes that collect the child's data overnight. However, unlike Level 1 PSG, the technician does not continuously monitor the signals overnight in real time. Instead, the signals are recorded overnight, and data are downloaded and analysed after the sleep study. Patients may also visit a local centre where staff would place the electrodes on the child who would then return home to do the sleep study.

MSAC noted that Level 2 PSG is already MBS listed for adults. MSAC acknowledged that there is a clinical need for this test, as current wait times for Level 1 PSG are unacceptably long (12–18 months). MSAC considered MBS listing of Level 2 PSG may help reduce wait times but was uncertain about how much it would reduce wait times. This is because a patient must be referred for the Level 2 PGS by a sleep physician and there are only 83 paediatric sleep physicians in Australia. However, MSAC noted the recent increase in trainees is expected to increase the number of paediatric sleep physicians.

MSAC also noted that Level 2 PSG is at least as safe and as accurate as Level 1 PSG. MSAC noted Level 2 PSGs have a higher testing failure rate than Level 1 PSG (failure rate of 9–19%), due to problems such as the sensors falling off during the night or the recording not working. However, Level 2 PSGs have many benefits such as being more convenient than Level 1 PSG, which may be particularly helpful for people living in rural and remote areas. Additionally, the proposed fee for Level 2 PSG is less than the fee for Level 1 PSG. Therefore, when a Level 2 PSG is performed instead of a Level 1 PSG it will potentially be cost saving to the government. It is expected that if Level 2 PSG is MBS funded, the demand for them will increase. MSAC also noted that out-of-pocket costs for MBS funded Level 1 PSG have been increasing and it was uncertain whether this will increase or decrease if Level 2 PSG is MBS listed. Overall, MSAC supported public funding of Level 2 PSG for children and adolescents, but advised that utilisation and out-of-pocket costs be reviewed after 2 years.

Consumer summary
MSAC's advice to the Commonwealth Minister for Health, Disability and Ageing MSAC supported MBS listing of Level 2 PSG for the diagnosis and management of sleep-disordered breathing in children (ages 3-11 years) and adolescents (ages 12-17 years). MSAC considered Level 2 PSG is at least as safe and accurate as Level 1 PSG, will help address equity of access, and would be good value for money. MSAC advised that utilisation and out-of-pocket costs should be reviewed after 2 years.

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

MSAC recalled that it had previously considered public funding of Level 2 PSG. In 2010 (MSAC Application 1130), MSAC supported MBS listing of Level 2 PSG for adults but did not support paediatric out-of-laboratory sleep studies due to a lack of comparative evidence and sparse linked evidence of effectiveness. In 2024 (MSAC Application 1712), MSAC considered but did not support MBS listing of Level 2 and 3 PSG in children and adolescents (ages 3 to <18 years). MSAC recalled that it had previously acknowledged that:

- there is a potential clinical need for Level 2 PSG
- compared to Level 1 PSG, Level 2 PSG has non-inferior accuracy, effectiveness and safety
- although Level 2 PSG is likely inferior in testing success (failure rates of 9–19%), this may be offset by the convenience and accessibility of home-based testing.

MSAC noted this re-application from the Australian Sleep Association was narrowed to seeking MBS funding for Level 2 PSG only and focussed on addressing MSAC's key matters of concern outlined in the Public Summary Document for MSAC Application 1712.

Regarding clinical need, MSAC noted data from 3 tertiary paediatric hospitals demonstrated wait times for medically uncomplicated patients are long (12-18 months). Limited data were available for the private sector, but MSAC noted that one private clinic reported no patients on their waitlist. Further, the applicant's data indicated approximately 30% of patients waiting for a Level 1 PSG would be suitable for a Level 2 PSG. MSAC considered the current wait times to be concerning and that there was a clear clinical need to increase testing capacity for children and adolescents.

MSAC noted there are only 83 registered paediatric respiratory and sleep physicians in Australia and access to paediatric sleep physicians may become the new barrier to accessing sleep studies. MSAC noted the applicant's pre-MSAC response clarified that long wait times for sleep studies are due to the limited capacity of sleep laboratories. The applicant's pre-MSAC response also stated the current wait times for paediatric sleep physicians had likely peaked. MSAC also noted that increased numbers of paediatric sleep trainees and the use of telehealth is expected to increase the number and capacity of paediatric sleep physicians. Further, adolescents can be referred for sleep studies by either an adult or paediatric sleep physician, which reduces pressure on paediatric sleep physicians. However, MSAC noted the resubmission did not consider the potential for increased demand for both sleep studies and referring sleep physicians if Level 2 PSG was available, including for children who are already receiving care in the private sector or who might not otherwise be tested. While MSAC considered that Level 2 PSG has the potential to reduce wait times for sleep studies, the extent to which Level 2 PSG will reduce wait times in practice remained uncertain.

MSAC noted that an appropriately qualified sleep physician is responsible for ensuring the test is performed appropriately and in accordance with professional guidelines. Further test performance oversight will be provided by the sleep technician who sets up the equipment (or supervises the parent or caregiver via telehealth) and provides technical assistance overnight to parents or caregivers (which is predicted to be rarely required, based on Australian experiences). MSAC noted the applicant's pre-MSAC response advised against using a community health provider to set up the equipment, as this would require extensive training. In addition, because the equipment would likely be applied during business hours, children may consequently wear the equipment for longer before bedtime which may be difficult for them to tolerate and sensors may move or be removed by children, potentially leading to higher test failure rates. MSAC considered referral for Level 2 PSG by a sleep physician to be important as it will ensure appropriate patient selection and reduce inappropriate use. MSAC also considered the technical oversight by a sleep technician to be important and that it should be specified in the MBS item descriptor.

MSAC noted the applicant had surveyed 6 parents whose children had previously undergone in-laboratory PSG. Responses suggested that telehealth-assisted equipment set-up is acceptable to families. Further, the parents noted that out-of-laboratory sleep studies would provide several benefits, including saving families time, money and travel, and providing a more comfortable environment for children. MSAC considered that, although in-person set-up is preferable, telehealth-assisted set-up is a reasonable alternative to address access and equity issues, and it should be available to all patients regardless of location and without needing to justify choosing this option.

MSAC considered that the reason for the service should be documented, to avoid inappropriate use, such as utilisation for monitoring the efficiency of continuous positive airway pressure (CPAP) treatment without a clinical reason. MSAC also considered that the explanatory notes should:

- specify that sleep studies that fail for technical reasons, such as unacceptable signal loss, and cannot meet the item descriptor in full are not eligible for reimbursement
- clearly state that repeat testing is for either
    - a failed or inconclusive test other than for failure due to technical issues
    - testing for residual disease, when required, following treatment
- clarify that videoconferencing is expected to be the default mode for telehealth but can be supplemented by telephone in geographic locations where video communication is difficult to establish or maintain
- clarify that, if using telehealth, technician support is to be provided throughout the process of applying the PSG equipment to the patient.

MSAC noted the cost breakdown for the proposed fees included professional services during equipment set-up (either in person or via telehealth), on-call technical support overnight, data download, analysis, scoring and interpretation. Costs also included consumables and shipping of equipment. MSAC noted that the proposed fees were higher than current fees for private home sleep studies (for children: $240 if fitted in rooms and $279 if fitted in the patient's home; set-up time of 30 minutes)[1]. MSAC considered that the proposed Level 2 PSG items and fees for children and adolescents should align with MBS item 12250 (Level 2 PSG for adults; fee of $391.10). MSAC noted that listing separate items for metropolitan and rural/remote patients (in Modified Monash 3-7 locations) was not consistent with the single MBS item for adult Level 2

[1] Queensland Children's Lung and Sleep Specialists (2025), *Brisbane sleep studies*, Queensland Children's Lung and Sleep Specialists, accessed 5 August 2025; Home Sleep Studies Australia (2025), *Sleep study services*, Home Sleep Studies Australia, accessed 5 August 2025.

PSG and could be avoided by adjusting the fee to cover set-up costs for all patients. MSAC considered the fees should include the additional cost component for telehealth set-up ($16.50) and a flat delivery cost component ($12.80, based on an estimate that 12.8% of the annualised population over 6 years will require equipment delivery and return, priced at $100). MSAC also considered the cost component for data download and analysis was over estimated and that 1 hour at $70/hour would be more appropriate. MSAC therefore considered the fee for Level 2 PSG for children and adolescents should be $466.30 and $433.30, respectively.

MSAC noted that many children living in rural and remote areas will be First Nations people, and queried whether there are equity concerns due to increased rates of test failures with Level 2 PSG. MSAC also noted that sleep studies that fail for technical reasons are ineligible for MBS reimbursement. Sleep laboratories may absorb the cost of a repeat test if the first test fails due to technical issues. However, MSAC considered it important to ensure parents are aware of this issue when considering a Level 2 PSG. MSAC also considered possible equity issues for children with disability but concluded that more complex patients would likely undergo a Level 1 PSG in a sleep laboratory or hospital setting for initial diagnosis and may undergo treatment monitoring at home if it is deemed appropriate by the sleep physician.

MSAC noted a revised cost-minimisation analysis was presented that incorporated changes to include delivery and set-up costs via telehealth. The revised economic evaluation reported the cost per diagnosis for Level 2 PSG was lower than that for Level 1 PSG resulting in a cost saving of $432.69 per accurate diagnosis. MSAC noted this cost saving was reasonable but was less than the estimate provided in the previous application (MSAC application 1712 estimated a cost saving of $645.29 per accurate diagnosis).

MSAC noted the revised financial analysis estimated that MBS listing of Level 2 PSG would initially be cost saving in year 1 (saving of $117,845 for children and $12,832 for adolescents) but from year 2 onwards there would be a modest increase in MBS expenditure (in year 6: increase of $1.2 million for children, $282,796 for adolescents). The additional cost from the second year onwards is due to the increased utilisation of Level 2 PSG compared to Level 1 PSG. MSAC considered the estimated utilisation to be reasonable based on the use of comparable items for adults, although the estimated use in rural and remote areas was likely overestimated. MSAC also noted that out-of-pocket costs with MBS funded Level 1 PSG has been increasing and it was uncertain whether this will increase or decrease if Level 2 PSG is MBS listed.

Overall, MSAC supported MBS listing of Level 2 PSG for the diagnosis and management of SDB in children and adolescents. MSAC noted adults are able to access MBS funded Level 2 PSG and that there is a clear clinical need for Level 2 PSG for children and adolescents to address the long wait times for sleep studies. MSAC also considered that Level 2 PSG is non-inferior in test accuracy, effectiveness and safety compared to Level 1 PSG in the proposed population. The economic evaluation indicated that Level 2 PSG is cost saving compared to Level 1 PSG, and the financial impact to the MBS is likely to be modest. MSAC supported the creation of 2 MBS items (as shown below) with revised fees that would ensure equitable access for all patients: one for children aged 3–11 with a fee of $466.30, and one for adolescents aged 12–17 with a fee of $433.30. MSAC also advised that the utilisation and out-of-pocket costs should be reviewed 2 years after implementation.

MSAC supported the availability of three publicly funded sleep studies per year, as is currently the case for Level 1 PSG (items 12210 and 12213), but clarified this means three studies in total of either type, not three of each.

Table 1 **MSAC supported item descriptor for paediatric Level 2 PSG in children aged 3-11 years (inclusive)**

Category 2: Diagnostic Procedures and Investigations **Group D1. Miscellaneous Diagnostic Procedures And Investigation** **Subgroup 10. Other Diagnostic Procedures And Investigations**
MBS item AAAA 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, or for assessment and titration of respiratory support, if: (a) the patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner; and (b) following professional attendance on the patient (either face to face or by video conference), the qualified paediatric sleep medicine practitioner has determined that the investigation is necessary and that an out-of-laboratory setting is appropriate for the sleep study; and (c) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 7 channels that include (i) to (vii) of-the following measures: (i) airflow; (ii) EEG; (iii) EMG; (iv) EOG; (v) ECG or heart rate; (vi) oxygen saturation; (vii) respiratory effort; (d) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner; and (e) either: (i) the equipment is applied to the patient by a sleep technician; or (ii) a sleep technician provides telehealth support to a parent or caregiver during the entire process while the parent or caregiver applies the equipment to the patient, the parent/caregiver is provided with written and/or videoed instructions describing the set-up process; and the use of telehealth during equipment set-up is documented; and (f) the parent or caregiver is provided with written and/or videoed instructions describing how to monitor the patient overnight, and a phone contact or data link to a sleep technician to enable trouble shooting overnight; and (g) 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 (h) the reason for the service is documented - either: (i) initial diagnosis; or (ii) repeat study for titration of respiratory support to optimize therapy; or to assess significant change in clinical status to determine the need for or the adequacy of respiratory support; and (i) interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine specialist with personal direct review of raw data from the original recording of polygraphic data from the patient; and (j) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203 For each patient – up to a maximum of 3 investigations from AAAA, BBBB, 12210 and 12213 in any 12-month period. **Fee:** $466.30 **Benefit:** 75% = $349.75 85% = $396.50 (See para DN.1.17 of explanatory notes to this Category)

Table 2 **MSAC supported item descriptor for paediatric Level 2 PSG in adolescents aged 12-17 years (inclusive)**

Category 2: Diagnostic Procedures and Investigations Group D1. Miscellaneous Diagnostic Procedures And Investigation Subgroup 10. Other Diagnostic Procedures And Investigations
MBS item BBBB 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, or for assessment and titration of respiratory support, if: (a) the patient has been referred by a medical practitioner to a qualified paediatric or adult sleep medicine practitioner; and (b) following professional attendance on the patient (either face to face or by video conference), a qualified paediatric or adult sleep medicine practitioner has determined that the investigation is necessary and that an out-of-laboratory setting is appropriate for the sleep study; and (c) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 7 channels that include (i) to (vii) of-the following measures: (i) airflow; (ii) EEG; (iii) EMG; (iv) EOG; (v) ECG or heart rate; (vi) oxygen saturation; (vii) respiratory effort; (d) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner; and (e) either: (i) the equipment is applied to the patient by a sleep technician; or (ii) a sleep technician provides telehealth support to a parent or caregiver during the entire process while the parent or caregiver applies the equipment to the patient; the parent/caregiver is provided with written/and or videoed instructions describing the set-up process, and the use of telehealth during equipment set-up is documented; and (f) the parent or caregiver is provided with written and/or videoed instructions describing how to monitor the patient overnight, and a phone contact or data link to a sleep technician to enable trouble shooting overnight; and (g) 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 (h) the reason for the service is documented - either: (i) initial diagnosis; or (ii) repeat study for titration of respiratory support to optimize therapy; or to assess significant change in clinical status to determine the need for or the adequacy of respiratory support; and (i) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine specialist with personal direct review of raw data from the original recording of polygraphic data from the patient; and (j) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735 and 12203. For each patient – up to a maximum of 3 investigations from BBBB, AAAA, 12210 and 12213 in any 12-month period. **Fee:** $433.30 **Benefit:** 75% = $325 85% = $368.50 (See para DN.1.17 of explanatory notes to this Category)

Other discussion

MSAC noted that usage of current paediatric Level 1 PSG MBS items for repeat investigations (12215 and 12217) was very low in the previous financial year, so suggested that the department explore the ongoing need for these items.

4. Background

The Medical Services Advisory Committee (MSAC) has previously considered out-of-laboratory sleep studies in the diagnosis and management of obstructive sleep apnoea (OSA) on 2 occasions: for adult and paediatric patients in (March 2010) and paediatric patients in (April 2024).

In 2010 , MSAC supported Level 2 polysomnography (PSG) studies for the investigation of OSA in adults on a referred basis (MSAC Application 1130). MSAC did not support public funding for Level 3 cardiorespiratory polygraphy (CRP) studies or Level 4 pulse oximetry studies for adults. For paediatrics, MSAC did not support any out-of-laboratory sleep studies because at the time of the application 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 PSG.

In 2024, MSAC considered but did not support 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 Application 1712). However, MSAC acknowledged there was a potential clinical need for Level 2 PSG and considered that Level 2 PSG studies are non-inferior in test accuracy, effectiveness and safety, although likely inferior in testing success (failure rates of 9-19%), compared to Level 1 PSG studies. MSAC acknowledged that inferior testing success may be offset by the convenience and accessibility of home-based testing.

Table 3 lists the key matters of concern raised in the Public Summary Document (PSD) for MSAC Application 1712, specifically for Level 2 PSG for diagnosis and management of SDB in children and adolescents, and how these are addressed in Application 1712.1.

Table 3 Summary of key matters of concern

Component	Matter of concern	How the current assessment report addresses it
Clinical need	Demonstrate a clear clinical need and provide a clear description of how the service will meet this need (PSD p.8).	Partially addressed. The application stated that the clinical need is to reduce long wait times for paediatric laboratory sleep studies by allocating some medically uncomplicated patients to the out-of-laboratory setting where bed space is not a capacity constraint. Data from 3 tertiary paediatric hospitals have been provided by the applicant to demonstrate wait times for medically uncomplicated patients (12-18 months). A single private clinic with no patients on their waitlist also provided data, which indicated private clinics may be an option for some patients (i.e. those who can afford to pay privately for a sleep study). The application stated that other paediatric sub-specialities (apart from paediatric sleep medicine) can refer their medically uncomplicated patients to other local community specialists, but this ability does not exist for paediatric sleep medicine practitioners requiring sleep studies for their medically uncomplicated patients. However, the assessment group notes that availability of 'local community specialists' may also be limited for other subspecialties. Patient-level data to enable calculation of actual wait times were not available. The extent to which the proposed service will impact wait times is uncertain.

Component	Matter of concern	How the current assessment report addresses it
Clinical need	Justify the estimate that 30% of wait-listed patients can be assessed with a Level 2 PSG in place of in-laboratory Level 1 PSG (PSD p.8).	Addressed. The application provided new data to demonstrate the proportion of patients on waitlists for Level 1 PSG who would be suitable for Level 2 PSG.
Clinical need	Explain 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 (PSD p.8).	Partially addressed. The application stated that this requirement will not change with the introduction of the proposed service as it is already required for access to Level 1 PSG. Access to paediatric sleep physicians has improved in recent years due to the availability of telehealth. The application did not consider the potential for increased demand for both sleep studies and referring sleep physicians if Level 2 PSG is available. As with current Level 1 PSG, adolescents can be referred by either an adult or paediatric sleep physician, spreading the demand across a larger pool of sleep medicine practitioners.
Proposal for public funding	Demonstrate how the proposed funding approach is aligned with the principle of a complete medical service and current MBS sleep study items (PSD p.9).	Addressed. Cost breakdown has been provided for the proposed fee, including postage for equipment and telehealth support for patients in regional and remote locations, and overnight access to technical support for all patients. Proposed fees are based on estimated time rather than on adult fees for unattended sleep studies.
Proposal for public funding	Demonstrate how the entire Level 2 PSG service will be funded, including all sources such as MBS and non-MBS funding, and taking into account how the following may be mitigated: - out-of-pocket costs - equity and access barriers. (PSD, p.9)	Addressed. Anticipated out-of-pocket costs include travel to collect the equipment from the sleep study provider. Measures to overcome equity and access barriers for rural and remote patients include: providing telehealth assistance for equipment set-up at the same cost as in-person set-up, which removes the need to travel to access a sleep study; and higher schedule fees attached to the item descriptors targeted at these patients, to account for the additional cost of equipment delivery (including return of equipment).
Proposal for public funding	Demonstrate a mechanism by which service providers can provide robust oversight to Level 2 PSG testing (PSD p.9). Ensure that: - parents/caregivers are properly briefed on how to use the equipment and the supervision of the child/adolescent required overnight, or - offer the option of a community health provider to attach the leads.	Partially addressed. The application stated that oversight is addressed by the requirement for the supervising physician to be appropriately qualified and take responsibility for appropriate performance of the test. The test would also be performed according to current professional guidelines (as is specified in the explanatory note for all currently listed MBS items for sleep studies). At a practical level, oversight is provided by the requirement for a sleep technician to either set up the equipment in person or supervise the parent/caregiver in doing so via telehealth, and access to technical help overnight. Use of a community health provider to set up the equipment was not considered an appropriate option in the application. No alternative models of care were suggested.
Economic analysis	Revise to incorporate the above considerations (PSD p.9).	Addressed. Economic analysis revised to incorporate changed funding request.
Financial analysis	Revise to incorporate the above considerations (PSD p.9).	Addressed. Financial analysis revised to incorporate changed funding request.

MBS = Medicare Benefits Schedule; PSD = Public Summary Document; PSG = polysomnography.
Source: Table 24 of MSAC Application 1712.1.

5. Prerequisites to implementation of any funding advice

The proposed services are performed under the supervision of a qualified paediatric sleep medicine practitioner (or adult sleep medicine practitioner for adolescents) using sleep monitoring sensors and equipment that are suitable 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).

In relation to Application 1712, MSAC noted that National Association of Testing Authorities (NATA) accreditation is not a current requirement for existing MBS sleep study items and may inadvertently restrict access to subsidised care. MSAC advised that NATA accreditation should not be a mandatory requirement for the delivery of Level 2 PSG services in paediatric patients.

6. Proposal for public funding

Currently, diagnosis of SDB in children and adolescents is undertaken in a sleep laboratory (Level 1 PSG) and this service is MBS listed. The proposed medical service is out-of-laboratory PSG, usually in the patients' homes (Level 2 PSG).

The application proposed four separate MBS items for children and adolescents and for services in rural/remote and metropolitan locations (Table 4). The Modified Monash (MM) Model was used to define whether a location is metropolitan, rural, remote or very remote, in keeping with its use in other MBS item descriptors. MM category 1 is a major city and MM category 7 is very remote.

The department proposed an alternative model involving two separate MBS items for children and adolescents (as per the application), plus one MBS item for Level 2 PSG undertaken in rural/remote areas to be applied as a loading for eligible patients.

All items for children (aged 3 to 11 years, inclusive) require consultation with, referral from, and oversight by a qualified paediatric sleep medicine practitioner. Items for adolescents (aged 12 to 17 years, inclusive) require consultation with, referral from, and oversight by either a qualified paediatric or adult sleep medicine practitioner. In contrast, adults can be referred to a diagnostic sleep study via a general practitioner (GP) without a consultation with a sleep practitioner or respiratory physician.

The requested frequency of the proposed paediatric MBS items is a maximum of 3 Level 2 PSG studies to be delivered to any one patient in any 12-month period.

Table 4 Summary of proposed MBS items for out-of-laboratory sleep studies (Level 2 PSG)

Proposed MBS Item	Age (years)	Proposed Schedule Fee	Purpose	Geographic location	Max. frequency (in 12 months)
DCAR 1712 PICO Set 1					
XXXX	Children (3 to 11, inclusive)	$415.65	Investigation of suspected OSA	Not specified	3 of any Level 2 PSG studies
YYYY	Adolescents (12 to 17, inclusive)	$364.32	Investigation of suspected OSA	Not specified	3 of any Level 2 PSG studies
Applicant proposal (DCAR 1712.1)					
AAAA	Children (3 to 11, inclusive)	$507.00	Investigation of suspected OSA	Not specified	3 Level 2 PSG studies
BBBB	Adolescents (12 to 17, inclusive)	$474.00	Investigation of suspected OSA	Not specified	3 Level 2 PSG studies
CCCC	Children (3 to 11, inclusive)	$623.50	Investigation of suspected OSA	MM 3-7	3 Level 2 PSG studies
DDDD	Adolescents (12 to 17, inclusive)	$590.50	Investigation of suspected OSA	MM 3-7	3 Level 2 PSG studies
Department proposal (DCAR 1712.1)					
AAAA	Children (3 to 11, inclusive)	$507.00	Investigation of suspected OSA	Not specified	3 of AAAA and BBBB
BBBB	Adolescents (12 to 17, inclusive)	$474.00	Investigation of suspected OSA	Not specified	3 of AAAA and BBBB
CCCC	Paediatric (3 to 17, inclusive)	$115	Investigation of suspected OSA – rural loading	MM 3-7	Not specified

DCAR = Department Contracted Assessment Report; MBS = Medicare Benefits Schedule; MM = Modified Monash category; OSA = obstructive sleep apnoea; PSG = polysomnography.
Source: Table 31 of MSAC Application 1712.1.

In the application proposal, the main difference in costs for studies undertaken in metropolitan and regional centres (MM 1 and 2) compared to rural and remote (MM 3 to 7) areas is the additional cost for equipment delivery and postage. This has been estimated at an average cost of $100, with acknowledgement that it would vary by location (device weighs approximately 3-5 kg and courier costs are up to $200 for deliveries to far north Queensland). After equipment has been posted, set up would be undertaken via telehealth; this would require additional time as the sleep technician is coaching the parent or carer rather than undertaking the set up themselves. The additional time was estimated at 15 minutes. For patients in metropolitan regions, the proposed MBS items also include the option for telehealth-assisted set up if a justification is provided.

In the PSD for Application 1712, MSAC advised that an alternative option would be for the leads to be attached by a trained health professional located in the community (such as pharmacists) but the applicant did not consider this an appropriate option for any Level 2 PSG services in any geographic location.

The department proposed basing the fee for a single modifier item on the applicant-proposed fee for postage. This item is intended to recognise the higher costs associated with service provision in regional and remote areas - these may include delivery of equipment, but the item is not prescriptive on how the service should actually be delivered to these patients.

The additional fee proposed in the application for telehealth set up in rural and remote areas is not included in the department proposal. The rationale is that if telehealth set up of equipment is an appropriate model, then it should be an option for all patients regardless of location. If there are concerns regarding telehealth equipment set up due to reduced test performance or safety, then additional justification is required to demonstrate that these risks are outweighed by the benefit of increased access for rural and remote patients.

A third option for equipment set up was included in the ratified PICO confirmation and DCAR 1712 but not in the resubmission. This option is for the sleep technician to attend the patients' home with the equipment and set it up there. This may entail higher costs for the sleep service due to technician travel and associated costs; however, it could reduce out-of-pocket costs for families and carers as they would not need to travel to collect and return equipment.

Regional centres (e.g. Ballarat, Albury, Toowoomba) are MM 2 locations, however they are not currently serviced by paediatric sleep laboratories and patients currently need to travel to metropolitan areas to access Level 1 PSG services. Under the proposals, these patients would be ineligible for the higher cost MBS items applicable for MM 3-7 but would likely face significant travel barriers if required to attend a laboratory to collect or be fitted with equipment. Consideration could be given to expanding access to the higher cost items to include patients in MM 2 locations. Under this approach, items CCCC and DDDD would be amended to be applicable to patients living in MM 2 to 7 locations. However, there is a risk that some patients with local access to paediatric sleep services would then be eligible for the items intended for rural and remote patients; for example, Darwin is MM 2 and has a paediatric sleep service. It should also be recognised that some patients living in MM 1 areas may face significant travel barriers (e.g. Rosebud to Monash Medical Centre in Victoria or Camden to Westmead Hospital in New South Wales) particularly where travel is required on consecutive days to collect and return equipment (compared to a Level 1 PSG that would require travel to the service, overnight stay, and return home the following day).

Set-up time varies between children and adolescents, with set up for younger children estimated to take around 30 minutes longer than in adolescents. This is because it is more challenging to correctly position the equipment on younger children.

The proposed fees are higher than for Level 2 PSG in adults, as adults have the option to apply the equipment themselves, enabling community-based testing models. In children and adolescents, where applying leads can be more difficult, it is more important to have a sleep technician available to provide support. Furthermore, automatic scoring of the sleep study – commonly used in adult studies – is less accurate in children and adolescents. Scoring must be performed manually by a suitably experienced technician, which takes longer than scoring in adults.

On-call technical support has been estimated at 0.3 hours per patient and would need to be available regardless of whether parents need it on any given night. In the case of providers also operating a Level 1 sleep laboratory, this support would typically be provided by overnight staff. It may be more challenging for providers that exclusively offer Level 2 PSG studies to provide this support.

There is an extensive explanatory note for sleep studies (DN.1.17) that could also be applicable for the proposed items. The department proposed that it be amended to clarify that video conference is expected to be the default mode for telehealth but can be supplemented by telephone in geographic locations where video communication is difficult to establish or maintain.

In its consideration of Application 1712, MSAC requested that a resubmission demonstrate a mechanism by which service providers can provide robust oversight to Level 2 PSG testing.

The application stated that oversight for testing is provided by the fact that:

1. Services need to be provided by a paediatric sleep service for children, and by a paediatric or adult sleep service for adolescents.
2. The supervising/billing physician takes responsibility for the appropriate performance of the test.
3. The test is performed according to 'current professional guidelines', noting this is already embedded in the Level 1 PSG items for paediatric and adult sleep study services (explanatory note DN.1.17).

A summary of key issues to be addressed in considering the proposed MBS items is presented in Table 5.

Table 5 Issues to be addressed in the proposed item descriptors

Issue	Description	Options
Telehealth	Telehealth is included as an option for all locations. In the applicant's proposal, a higher fee for this is proposed for patients in MM 3–7 locations. There was insufficient evidence available in DCAR 1712 to support or refute telehealth.	• Telehealth appropriate for all patients regardless of geographic location • Telehealth appropriate only where benefits outweigh risks (lack of access versus safety and performance of test) • Telehealth not appropriate
Delivery costs	Flat rate for patients in MM 3–7 location proposed by applicant. Rate is used as basis for departments proposed modifier; however, department states that modifier item recognises that service provision entails additional costs in rural and remote locations and renumerates for this, but not necessarily directly, or only, through postage. Additional out-of-pocket costs could still be applied. Delivery may still be required in MM 1–2 areas where patients are accessing the service via telehealth.	• Add wording to modifier to mandate bulk billing or prevent out-of-pocket costs • Consider whether delivery cost is the most suitable basis for the modifier fee
Geographic location	There are MM 2 locations (and some MM 1 locations) with very limited access to paediatric sleep services. There are also paediatric sleep services in an MM 2 location (Darwin) although the sleep medicine practitioner is based in Sydney. Unclear how proposal would impact on these existing services.	• Consider whether MM 2–7 or MM 3–7 is most suitable for the modifier • Apply modifier where patient location is at a distance from provider (e.g. patient in MM 2–7 location and at least 60 km by road from provider [e.g. MBS item 294]).
Scoring of study	Proposed item descriptor (and current paediatric item descriptors) do not differ from adult with respect to scoring and allows for 'manual correction of computerised scoring'. Applicant advises paediatric studies require manual scoring.	• Remove reference to computerised scoring in the descriptor

DCAR = Department Contracted Assessment Report, MM = Modified Monash.
Source: Table 34 of MSAC Application 1712.1.
); MBS = Medical Benefits Schedule.
Source: Table 38 of MSAC Application 1712.1.

Proposed MBS item descriptors

The 4 item descriptors proposed by the applicant are shown on page 4-10 of MSAC 1712.1 Application Summary. The 3 alternative item descriptors proposed by the department are shown in Table 6 to Table 8. The 2 MBS items supported by MSAC with revised fees and reasoning for simplifying the items are shown Section 3 of this document.

Table 6 **Department proposed item descriptor for paediatric Level 2 PSG in children aged 3-11 years (inclusive)**

Category 2: Diagnostic Procedures and Investigations **Group D1. Miscellaneous Diagnostic Procedures And Investigation** **Subgroup 10. Other Diagnostic Procedures And Investigations**
MBS item AAAA Overnight investigation of sleep for at least 8 hours, for a patient aged at least 3 years but less than 12 years, to confirm diagnosis of obstructive sleep apnoea, if: (a) the patient has been referred by a medical practitioner to a qualified paediatric sleep medicine practitioner; and (b) following professional attendance on the patient (either face to face or by video conference), a qualified paediatric sleep medicine practitioner has determined that the 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 (c) during a period of sleep, there is continuous monitoring and recording performed in accordance with current professional guidelines, of a minimum of 7 channels that include (i) to (vii) of the following measures: (i) airflow; (ii) EEG; (iii) EMG; (iv) EOG; (v) ECG or heart rate; (vi) oxygen saturation; (vii) respiratory effort; (d) the investigation is performed under the supervision of a qualified paediatric sleep medicine practitioner; and (e) either: (i) the equipment is applied to the patient by a sleep technician; or (ii) if this is not possible, a sleep technologist provides telehealth support to a parent or caregiver while the parent or caregiver applies the equipment to the patient; and A. telehealth support is provided during the entire process of applying the equipment to the patient; B. telehealth is supported by written and/or videoed instructions provided to the parent/caregiver; C. the use of telehealth during equipment set up is documented; and D. the reason it is not possible for a sleep technologist to apply the equipment to the patient is documented; and (f) written instructions are given to the parent or caregiver describing how to monitor the patient overnight, and a phone contact or data link to the sleep technician to enable trouble shooting overnight is provided; and (g) 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 (h) interpretation and preparation of a permanent report is provided by a qualified paediatric sleep medicine practitioner with personal direct review of raw data from the original recording of polygraphic data from the patient; and (i) 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, 11713, 11714, 11716, 11717, 11723, 11735 and 12213 Up to a maximum of 3 sleep study items per patient from AAAA and BBBB in any 12-month period. **Fee:** $507.00 **Benefit:** 75% = $380.25 85% = $430.95 (See para DN.1.17 of explanatory notes to this Category)

ECG = electrocardiogram (electrocardiography); EEG = electroencephalogram (electroencephalography); EMG = electromyogram (electromyography); EOG = electrooculogram (electrooculography); MBS = Medical Benefits Schedule; PSG = polysomnography.
Source: Table 39 of MSAC Application 1712.1.

Table 7 Department proposed item descriptor for paediatric Level 2 PSG in adolescents aged 12-17 years (inclusive)

Category 2: Diagnostic Procedures and Investigations
Group D1. Miscellaneous Diagnostic Procedures And Investigation
Subgroup 10. Other Diagnostic Procedures And Investigations

MBS item BBBB

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) the patient has been referred by a medical practitioner to a qualified paediatric or adult sleep medicine practitioner; and

(b) following professional attendance on the patient (either face to face or by video conference), a qualified paediatric sleep medicine practitioner has determined that the 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

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

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

(d) the investigation is performed under the supervision of a qualified paediatric or adult sleep medicine practitioner; and

(e) either:

- (i) the equipment is applied to the patient by a sleep technician; or
- (ii) if this is not possible, a sleep technologist provides telehealth support to a parent or caregiver while the parent or caregiver applies the equipment to the patient; and
  - A. telehealth support is provided during the entire process of applying the equipment to the patient;
  - B. telehealth is supported by written and/or videoed instructions provided to the parent/caregiver;
  - C. the use of telehealth during equipment set up is documented; and
  - D. the reason it is not possible for a sleep technologist to apply the equipment to the patient is documented; and

(f) written instructions are given to the parent or caregiver describing how to monitor the patient overnight, and a phone contact or data link to the sleep technician to enable trouble shooting overnight is provided; and

(g) 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

(h) interpretation and preparation of a permanent report is provided by a qualified paediatric or adult sleep medicine practitioner with personal direct review of raw data from the original recording of polygraphic data from the patient; and

(i) 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, 11713, 11714, 11716, 11717, 11723, 11735 and 12213

Up to a maximum of 3 sleep study items per patient from AAAA and BBBB in any 12-month period.

Fee: $474.00 **Benefit:** 75% = $355.50 85% = $402.90

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

ECG = electrocardiogram (electrocardiography); EEG = electroencephalogram (electroencephalography); EMG = electromyogram (electromyography); EOG = electrooculogram (electrooculography); MBS = Medical Benefits Schedule; PSG = polysomnography.
Source: Table 40 of MSAC Application 1712.1.

Table 8 Department proposed item descriptor for a rural loading for paediatric patients

Category 2: Diagnostic Procedures and Investigations Group D1. Miscellaneous Diagnostic Procedures And Investigation Subgroup 10. Other Diagnostic Procedures And Investigations
MBS item CCCC
Overnight investigation of sleep for at least 8 hours, for a patient aged at least 3 years but less than 18 years, to confirm diagnosis of obstructive sleep apnoea, if: (a) item AAAA or BBBB applies; and (b) the patient has been assessed as appropriate for an out-of-laboratory setting; and (c) the service is a referred service; and (d) the patient is not an admitted patient of a hospital; and (e) other than application and removal of equipment, the service is not provided at a practice location operated by the sleep study provider;; and (f) the patient is located within a Modified Monash 3, 4, 5, 6 or 7 area at the time of the service; and (g) the service is provided by a medical practitioner whose practice location is not in a Modified Monash area mentioned in paragraph f.
Fee: $115.00 **Benefit:** 85% = $97.75
(See para DN.1.17 of explanatory notes to this Category)

Source: Table 41 of MSAC Application 1712.1.

Explanatory note relating to existing sleep study MBS items

Explanatory note DN.1.17 is shown in Table 9. Changes to this note have not been proposed in the application; however, it could be used to specify any additional requirements specific to paediatric Level 2 PSG, particularly in relation to manual scoring or manual correction of computerised scoring in paediatric patients. The department proposes the note be amended to clarify that video conference is expected to be the default mode for telehealth but can be supplemented by telephone in geographic locations where video communication is difficult to establish or maintain.

Table 9 Explanatory note DN.1.17 for existing sleep study items

		Category 2 - DIAGNOSTIC PROCEDURES AND INVESTIGATIONS
DN.1.17		**Investigations for sleep disorders (Items 12203 to 12250)**
MBS Item	**Service type**	**Study Level**
12203		1
12204		1
12205	Adult sleep study in Laboratory	1
12207		1
12208		1
12210		1
12213	Paediatric sleep study in laboratory	1
12215		1
12217		1
12250	Adult sleep study – unattended	2

NB. Currently there are no MBS items available for levels 3 and 4 sleep studies.

Applicable Guidelines

Guidelines for the performance of sleep studies in adults – a position statement of the Australasian Sleep Association

The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events: rules, terminology and technical specifications relating to the provision of polysomnography (PSG).

An Australian Commentary on the AASM Manual for the Scoring of Sleep and Associated Events relating to the provision of polysomnography (PSG).

Current Professional Guidelines:

Items 12203 to 12250 require the continuous monitoring and recording of all listed parameters that are measured and performed in accordance with the current professional guidelines.

This means practitioners are required to ensure they are able to meet the polysomnography (PSG) requirements including technical specifications and electrode placements in the following documents:

- Guidelines for the performance of sleep studies in adults – a position statement of the Australasian Sleep Association. Refer to the document under the heading Sleep Studies in Adults - Position statements (sleep.org.au)
- The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events: rules, terminology and technical specifications (you will require an account to access this resource). Refer to the section Sleep Staging Rules in the AASM Scoring Manual - American Academy of Sleep Medicine
- An Australian Commentary on the AASM Manual for the Scoring of Sleep and Associated Events. Refer to the document under the heading Scoring of Sleep and Associated Events - Position statements (sleep.org.au)

Please note that for MBS purposes Home Sleep Apnoea Test (HSAT) requirements in the above documents apply to levels 3 and 4 sleep studies and are therefore not applicable for MBS items 12203 to 12250.

Referral Criteria in items 12203 and 12250

Items 12203 and 12250 are applicable for patients who require a diagnostic sleep study. They enable direct GP referral to a diagnostic sleep study without personal assessment by a sleep or respiratory physician, when validated screening questionnaires suggest a high pre-test probability for diagnosis of symptomatic, moderate to severe obstructive sleep apnoea (OSA). The screening questionnaires should be administered by the referring practitioner. Alternatively, the need for testing can be determined by a sleep or respiratory physician following direct clinical assessment (either face-to-face or by video conference).

Screening Questionnaires

For the purpose of items 12203 or 12250, a high probability for symptomatic, moderate to severe OSA would be indicated by one of the following clinical screening tool outcomes:

- STOP-Bang score of 3 or more AND an Epworth Sleepiness Scale score of 8 or more;

OR

- OSA50 score of 5 or more AND an Epworth Sleepiness Scale score of 8 or more;

OR

- high risk score on the Berlin Questionnaire AND an Epworth Sleepiness Scale score of 8 or more.

The STOP-Bang, OSA50, Berlin questionnaires and Epworth Sleepiness Scale can be accessed at Douglas et al, Guidelines for sleep studies in adults - a position statement of the Australasian Sleep Association. Sleep Med. 2017 Aug; 36 Suppl 1:S2-S22 (www.sleep.org.au/documents/item/2980) or on the American Thoracic Society website (www.thoracic.org/members/assemblies/assemblies/srn/questionaires/).

Evidence of the screening tests being administered to the patient in full, including screening test scores must be recorded in the patient's clinical record as this may be subject to audit.

Please note that the presence of a high probability for symptomatic, moderate to severe obstructive sleep apnoea in a patient does not mean a study can be provided under either 12203 or 12250 utilising the HSAT guidelines. The service being delivered must meet all the requirements contained in the MBS item number being claimed regardless of patient risk for obstructive sleep apnoea (which would be in accordance with the PSG guidelines).

Referrals for attended (Level 1) or unattended (level 2) diagnostic studies

Where a patient with suspected OSA has been directly referred for a Level 1 sleep study under item 12203, but there is insufficient information to indicate if there are any contraindications for a Level 2 study, the following options are available:

The patient can be assessed by a qualified sleep medicine practitioner or consultant respiratory physician to determine the most suitable study (i.e. Level 1 or Level 2); or

- The validated screening questionnaires can be administered to the patient by the sleep medicine practitioner, sleep technician or practice staff. If the screening questionnaires indicate a high pre-test probability for the diagnosis of symptomatic, moderate to severe OSA, the sleep provider can either – arrange for the patient to have a Level 2 study (notifying the referring practitioner of this decision); or seek additional information from the referring practitioner on why a Level 1 study is required (e.g. whether the patient has any contraindications for a Level 2 study). If there remains any uncertainty about the type of study which the patient should receive, a qualified sleep medicine practitioner or consultant respiratory physician should assess the patient.

Referrals made without (or incomplete) screening questionnaires (Items 12203 and 12250)

- If a patient has been directly referred to a qualified sleep medicine practitioner or consultant respiratory physician without the use of the screening questionnaires, the screening questionnaires can be administered to the patient by the sleep provider (e.g. by a sleep technician or other practice staff). Where the screening questionnaires have been provided with the referral, but they are incomplete, the sleep provider may wish to contact the patient to determine what their responses were to the relevant questions.

Attended (Level 1 study) versus unattended (Level 2 study) sleep studies

Determination of the need for a sleep study should conform with Australasian Sleep Association guidelines.

Unattended sleep studies are suitable for many patients with suspected OSA but patients with other sleep disorders should undergo an attended study. Assessment for potential contraindications to an unattended sleep study can be undertaken by either the referring practitioner, qualified adult sleep medicine practitioner or consultant respiratory physician. Standardised referrals should request sufficient information to enable such assessment.

In accordance with the Australasian Sleep Association's Guidelines for Sleep Studies in Adults, relative contraindications for an unattended sleep study to investigate suspected OSA include but are not limited to:

(a) intellectual disability or cognitive impairment;

(b) physical disability with inadequate carer attendance;

(c) significant co-morbid conditions including neuromuscular disease, heart failure or advanced respiratory disease where more complex disorders are likely;

(d) suspected respiratory failure where attended measurements are required, including measurement of carbon dioxide partial pressures;

(e) suspected parasomnia or seizure disorder;

(f) suspected condition where recording of body position is considered to be essential and would not be recorded as part of an unattended sleep study;

(g) previously failed or inconclusive unattended sleep study;

(h) unsuitable home environment including unsafe environments or where patients are homeless; and

(i) consumer preference based on a high level of anxiety about location of study or where there is unreasonable cost or disruption based on distance to be travelled, or home circumstances.

Patients who have these features may be suitable for either attended (Level 1) or unattended (Level 2) studies.

Treatment options following testing

The results and treatment options following any diagnostic sleep study should be discussed during a professional attendance with a medical practitioner before the initiation of any therapy. If there is uncertainty about the significance of test results or the appropriate management for that individual then referral to a sleep or respiratory medicine specialist is recommended. Any professional attendance by a qualified sleep medicine practitioner or consultant respiratory physician associated with this service may be undertaken face-to-face or by video conference.
Meaning of 'at least 8 hours' The requirement 'for at least 8 hours' means the overnight investigation (including patient set-up time and actual period of recording) must be of at least 8 hours duration. Providers must keep evidence of the duration of the overnight investigation (including set-up time and period of recording) as part of their administrative records for MBS sleep studies.
Polygraphic data Item 11503 is not for the purpose of investigation of sleep disorders. Polygraphic data obtained as part of a sleep study item in the range 12203 to 12250 cannot be used for the purpose of claiming item 11503.
Billing requirements for level 1 and 2 sleep studies All items are subject to MBS compliance processes and activities, including random and targeted audits which may require a provider to submit evidence about the services claimed. For sleep studies this would include a full copy of the PSG record that includes the raw data. The written report issued at the completion of the sleep study should include all of the requirements listed in the relevant clinical guidelines for types 1 and 2 sleep studies. Items 12203 to 12250 do not support a figurehead billing arrangement. Figurehead or 'headline' billing is where one practitioner's provider number is used to bill patients for the services provided by other practitioners. While individual components of the sleep study service (e.g. supervision of the investigation and interpretation and preparation of a permanent report) do not need to be performed by the same qualified sleep medicine practitioner, it is an MBS requirement that the qualified sleep medicine practitioner who prepared the report on the results of the investigation bill the relevant item. Benefits are not payable for items 12203 to 12250 where the interpretation and preparation of a permanent report is provided by a technician or supervised staff rather than by a qualified sleep medicine practitioner. Where the date of service for a sleep study item is the same as the date of service of any items 11000 to 11005, 11503, 11713 and 12203/12250, for a benefit to be payable, there must be written notification on the account identifying that the service under any of those items was not provided on the same occasion as the sleep study item. The date of service for the purposes of items 12203 to 12250 is deemed to be the day of the morning the overnight investigation is completed. Billing for the service must only occur once all of the requirements of the item have been fulfilled.
Related Items: 12203 12204 12205 12207 12208 12210 12213 12215 12217 12250

AASM = American Academy of Sleep Medicine; GP = general practitioner; HSAT = home sleep apnoea test; MBS = Medicare Benefits Schedule; OSA = obstructive sleep apnoea; PSG = polysomnography.
Source: Medicare Benefits Schedule (14 May 2025).

Clinical need

The re-application clarified the clinical need as addressing wait times, claiming that the primary delay in accessing sleep studies at tertiary paediatric hospitals in Australia occurs between consultation with a specialist sleep physician and completion of a Level 1 PSG. The average waiting time for a clinic appointment with a paediatric sleep physician is estimated at 3-6 months (with telehealth now available) and is not expected to change with the proposed service. However, the average waiting time for a Level 1 PSG after seeing the specialist is significantly longer – estimated at 12-18 months for medically uncomplicated patients.

In-laboratory sleep studies have a fixed capacity based on bed numbers and staffing. The following annual capacities are cited for 3 tertiary paediatric hospitals in Australia:

- Sydney Children's Hospital Westmead – 1,000/year (20 studies per week [4 beds], 5 nights maximum)
- Royal Children's Hospital – 552/year (12 studies per week operating 46 weeks per year)

- Queensland Children's Hospital – 1,380/year (30 studies per week [6 beds], 5 nights maximum for 46 weeks per year).

The number of requests for in-laboratory sleep studies at Queensland Children's Hospital in 2023 was 1,425 and for the Royal Children's Hospital in 2024 it was 632. Therefore, requests exceed capacity in these settings and less urgent (low acuity) patients wait the longest. Limited data are available for the private sector, however the application stated that Sydney Adventist Hospital provided in-laboratory sleep studies to 49 paediatric patients in November 2024 and had no patients on the waitlist. Data on patient-level wait times (e.g. median, longest etc.) were not available.

In out-of-laboratory settings, capacity would be limited by equipment availability and staffing capacity for set-up and reporting, but would not be capped by physical bed spaces. The proposed service would target medically uncomplicated patients currently waiting for a sleep study.

The provision of Level 2 PSG services also aims to improve equity for paediatric patients by aligning access with that available to adults and improving access in rural and remote locations, where paediatric sleep laboratories are not typically located.

Unlike adults, adenotonsillectomy represents first line treatment for children with OSA. According to the PSD for MSAC Application 1712, 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. ESC and MSAC supported the referral of adenotonsillectomy (MBS item 41789) to the MBS Review Advisory Committee on the basis of variation in service number and mixed evidence of improved outcomes for OSA. The application does not cite any potential impact of the proposed service on the rate of inappropriate/appropriate tonsillectomies.

7. Population

In adults, OSA is most commonly associated with obesity. In children, the leading cause is enlarged tonsils and adenoids, which grow most rapidly during the pre-school years – resulting in a peak incidence of OSA between 2 and 8 years of age. Ear, nose and throat (ENT) surgery, mainly adenotonsillectomy, is the mainstay of initial treatment for paediatric OSA. Level 1 PSG is considered the gold standard for diagnosing and assessing the severity of OSA. However, it is not always readily available, is time consuming, and requires referral and interpretation by a sleep specialist for MBS reimbursement. As a result, most children undergo tonsillectomy based on a clinical diagnosis of OSA, without confirmation by PSG.

Children with certain underlying medical conditions – especially those involving muscle weakness, hypotonia and craniofacial abnormalities – are at increased risk of developing OSA. Their breathing disorders are often more complex and multifactorial, making them more likely to experience residual OSA after initial treatment for OSA and to require repeat or ongoing sleep studies.

The proposed population included children and adolescents assessed by a qualified sleep medicine practitioner as requiring PSG confirmation of suspected moderate to severe OSA, and for whom an out-of-laboratory setting was considered appropriate. The proposed intervention for this population was a Level 2 PSG study to diagnose OSA.

The population was limited to uncomplicated cases. High risk patients – such as those with a risk of hypoventilation (including obesity hypoventilation) or complex comorbidities (e.g. cardiac conditions) – were deemed unsuitable for Level 2 PSG. The proposed intervention was for the investigation of suspected OSA and excluded patients with suspected sleep movement disorders,

nocturnal seizures, atypical parasomnias, hypersomnia, narcolepsy, or those commencing respiratory support.

The proposed population for Level 2 PSG studies is children aged 3 years to less than 12 years; as children younger than 3 years should only be evaluated in an in-laboratory setting.

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

8. Comparator

The comparator for PICO Set 1 is a diagnostic Level 1 (in-laboratory) PSG study under MBS item 12210 for children or 12213 for adolescents.

9. Summary of public consultation input

The previous MSAC 1712 application received input from four (4) professional organisations and (1) consumer organisation. This feedback was largely supportive and can be found in Section 9 of the Public Summary Document for MSAC Application 1712.

New consultation input was welcomed from two (2) professional organisations for this resubmission. The organisations that submitted input were:

- The Thoracic Society of Australia & New Zealand (TSANZ)
- Prader Willi Research Foundation Australia (PWRFA).

Level of support for public funding

Both organisations expressed support for the public funding of the application, with TSANZ requesting further consultation and information regarding the proposed services in First Nations communities.

Comments on PICO

- PWRFA noted that children and adolescents with neurodevelopmental conditions, particularly those with rare, high-support needs like Prader Willi Syndrome (PWS) should be considered a priority population for access. PWRFA noted these are individuals who are:
    - At high risk for undiagnosed and untreated sleep disordered breathing
    - Often unable to tolerate overnight hospital stays
    - Underserved by current hospital-based sleep services

Perceived Advantages

- PWRFA noted that out-of-laboratory sleep studies offer an alternative that is:
    - More accessible for families in rural or remote areas
    - Better tolerated by children with intellectual disability, autism, or sensory needs
    - Able to detect clinically significant events requiring timely intervention
- PWRFA noted that access to timely sleep studies is critical for individuals with PWS, as a sleep assessment is required prior to initiating growth hormone (GH) therapy, and early initiation of GH therapy is associated with a range of vital benefits.

Support for Implementation and Issues

- TSANZ endorsed the proposed >50km threshold for oximetry and agreed that additional attention is needed for costing in remote and very remote areas, especially within the

Northern Territory (NT), Queensland (QLD), and Western Australia (WA). TSANZ also noted that light aircraft are commonly used for outreach visits in the NT, often dedicating at least a day to such trips, which would significantly increase associated costs.

- TSANZ noted that the application does not currently list any Aboriginal health organisations as having been consulted, nor does it mention potential impacts for Aboriginal Australian children. TSANZ outlined that in remote and very remote regions of the NT, QLD, and WA, Aboriginal Australians constitute a significant proportion of the population, many of whom may potentially utilise the proposed overnight oximetry. Therefore, TSANZ provided the following recommendations:
    - Detail consultations with Aboriginal health organisations.
    - Outline the potential impacts and benefits for Aboriginal Australian children.
    - Describe how the proposed services will be made culturally appropriate and accessible to Aboriginal Australian communities, particularly in remote and very remote settings.
- PWRFA provided the following recommendations for implementation:
    - That out-of-laboratory sleep studies be publicly funded for all children and adolescents, with priority consideration given to those with disability, rare conditions, or complex needs.
    - That access be nationwide, including for families in regional and remote areas.
    - The service includes clear clinical pathways for referral, follow-up, and escalation to in-lab testing if required.
    - That training and resources be developed to ensure these studies are conducted and interpreted accurately in paediatric populations.

10. Characteristics of the evidence base

The characteristics of the evidence base, and summary of comparative safety and effectiveness, is unchanged from MSAC Application 1712 and has been reproduced below.

For Level 2 PSG, 2 studies 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 five single-arm cohort studies that assessed the test reliability of Level 2 PSG.

Table 10 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 text compared to reference standard. Reference standard is also the comparator.	☒ k = 2 n = 87	QUADAS-2: overall most studies had moderate risk of bias
Test reliability	Comparative and single arm studies	Comparative studies: ☒ k = 2 n = 87 Single arm studies: ☒ k = 5 n = 708	NHLBI quality assessment tool for case series studies: Low risk in 2 studies, moderate to high risk in the remainder.
Safety	One single-arm cohort study reported safety of the test. No other studies met the inclusion criteria for safety outcomes.	☒ k = 1 n = 233	NHLBI quality assessment tool for case series studies: Low risk

k = number of studies; n = number of patients; NHLBI = National heart, lung, and blood institute; QUADAS-2 = quality assessment of diagnostic accuracy studies tool for comparison of an index test with a reference standard.
Source: Table 6 of MSAC Application 1712.

11. Comparative safety

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

12. Comparative effectiveness

Test accuracy

Two studies reported test accuracy of Level 2 PSG studies compared to Level 1 PSG studies.

Withers et al. (2022)[2] 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)[3] (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

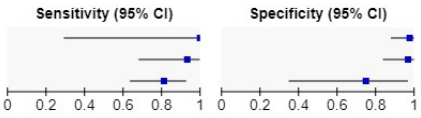
[2] Withers et al. (2022) 'Comparison of home ambulatory type 2 polysomnography with a portable monitoring device and in-laboratory type 1 polysomnography for the diagnosis of obstructive sleep apnea in children', *J Clin Sleep Medicine*, 18(2): 393-402, doi: 10.5664/jcsm.9576.

[3] Cielo et al. (2023) 'Feasibility and performance of home sleep apnea testing in youth with Down syndrome', *J Clin Sleep Medicine*, 19(9): 1605-1613. doi: 10.5664/jcsm.10610.

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**

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Withers (2022) - moderate to severe OSA	3	1	0	43	1.00 [0.29, 1.00]	0.98 [0.88, 1.00]
Withers (2022) - any OSA	14	1	1	31	0.93 [0.68, 1.00]	0.97 [0.84, 1.00]
Cielo (2023) - moderate to severe OSA	26	2	6	6	0.81 [0.64, 0.93]	0.75 [0.35, 0.97]



CI = confidence interval; FN = false negative; FP = false positive; OSA = obstructive sleep apnoea; PSG = polysomnography; TN = true negative; TP = true positive.
Notes: Withers did not report the AHI/OAHI values used for each diagnostic threshold. Moderate to severe OSA in Cielo (2023) was OAHI > 5/h.
Source: Figure 1 of MSAC Application 1712.

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 2 cross-sectional accuracy studies. An additional 5 single-arm studies reported initial Level 2 test failure rates ranging from 9-19%.

Change in management

No change in management studies were identified that met the inclusion criteria, nor were 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.

13. Economic evaluation

Consistent with ADAR 1712, a cost-minimisation analysis was undertaken.

The cost-minimisation approach considered the proportion of failed sleep studies, diagnostic accuracy, and costs to estimate a cost per accurate diagnosis. Treatment implications and health outcomes beyond the diagnosis were not considered. The time frame was set to 1 year as this was considered an appropriate time horizon for capturing occasions of repeated sleep studies. The 3 MBS items suggested by the department were used in the base case (the impact of using the 4 MBS items proposed by the applicant were tested in a sensitivity analysis and had minimal impact on the cost per accurate diagnosis).

Table 11 provides a summary of the approach.

Table 11 Summary of the economic evaluation

Component	Description
Therapeutic claim: effectiveness	Based on evidence presented in DCAR 1712, effectiveness is assumed to be non-inferior
Therapeutic claim: safety	Based on evidence presented in DCAR 1712, 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

DCAR = Department Contracted Assessment Report.
Source: Table 42 of DCAR 1712.1.

The clinical inputs used in the cost-minimisation analysis were consistent with those used in DCAR 1712 (Table 14).

Table 12 Clinical inputs in the base case analysis

Input	Value	Source
Diagnostic accuracy (treatment threshold – moderate to severe)	Sensitivity 1.00 (0.29-1.00) Specificity 0.98 (0.88 – 1.00)	Withers et al. 2022 (see Appendix A, Table 44)
Prevalence	40%	Assumption – clinical experts
Level 1 PSG failed test rate	0%	Assumption – consistent with Application 1130
Level 2 PSG failed (and inconclusive) test rate	10%	Griffiths et al. 2022 (see Appendix A, Table 45)
Second Level 2 PSG failed (and inconclusive) test rate	6%	Assumption based on Appendix A (Table 45)
Following failed Level 2 PSG test	50% repeat Level 2 PSG tests, 50% have Level 1 PSG test. No separate rate for 'inconclusive test' available. After second failure, all retested with Level 1 PSG.	Assumption

PSG = polysomnography.
Source: Table 43 of DCAR 1712.1.

The costs considered in the economic evaluation were from a health system perspective (Table 13). The approach to derive costs is consistent with DCAR 1712, although more recent sources have been used.

Table 13 Summary of the costs included in the cost-minimisation approach

Parameter	Value	Source
Direct health service costs		
Cost of Level 2 PSG (intervention)	$523.46	Table 25. Weighted average assuming 18.7% of testing performed in adolescents and 81.3% in children (based on MBS claiming data for items 12210 and 12213, respectively, for FY 2023-24)[a] and weighted for % of total population (all ages) residing in MM 1-2 (80%) vs MM 3-7 (20%) (derived from Versace et al. 2021, Table 1).
Cost of Level 1 PSG (comparator)	$784.77	Weighted average assuming 18.7% in adolescents and 81.3% in children (based on MBS claiming data for items 12210 and 12213, respectively, for FY 2023—24).
Additional costs and/or cost offsets		
Initial consult with general practitioner	$82.90	MBS Item 36, May 2025.
Consultant physician attendance, initial	$174.50	MBS Item 110 (or telehealth Item 91824), May 2025.
Consultant physician attendance, follow-up	$87.30	MBS Item 116 (or telehealth Item 91825), May 2025.
Out-of-pocket costs for Level 2 PSG	$10.50	Based on MBS estimated costs[b] for MBS item 12250 (i.e. adult unattended study).
Out-of-pocket costs for Level 1 PSG	$37.13	Based on MBS estimated costs[c] for MBS item 12203 (i.e. adult attended study – data not available for Level 1 studies in children aged 3-11 years, inclusive).
Travel costs for Level 2[d]	$0.00	-
Travel costs for Level 1	$69.27	Based on ATO cost/km of 88 cents for 400 km[e], and weighted for % of total population (all ages) residing in MM 1-2 (80%) vs MM 3-7 (20%) (Versace et al. 2021).[f]

ATO = Australian Taxation Office; FY = financial year; MBS = Medicare Benefits Schedule; MSAC = Medical Services Advisory Committee; MM = Modified Monash category, PSG = polysomnography.
a. The base case in DCAR 1712 assumed 18.5% adolescents and 81.5% children.
b. 14% had an out-of-pocket cost, typically $150, based on 'Medical Costs Finder' MBS resource.
c. 33% had an out-of-pocket cost, typically $225, based on 'Medical Costs Finder' MBS resource.
d. Travel costs applied to Level 1 PSG only as people undergoing Level 2 PSG would not need to travel to collect equipment if they live far from the sleep centre and could instead have the equipment couriered to them and applied via telehealth.
e. Based on Australian Taxation Office claimable deductions for motor vehicle expenses.
f. DCAR 1712 assumed the proportion of services in rural/remote locations was 38% based on 2021-2022 data from the Australian Institute of Health and Welfare for hospital admission rates for tonsillectomies by region. This input was changed for the resubmission to 20% based on MM categories in order to align with the proposed MBS items.
Source: Table 44 of DCAR 1712.1.

Consistent with DCAR 1712, the base case results are presented in terms of cost per accurate diagnosis, assuming that Level 2 PSG has non-inferior test accuracy and inferior test success compared to Level 1 PSG (noting the cost of outcomes following diagnosis have not been considered in the analyses).

As shown in Table 14, the proposed out-of-laboratory Level 2 PSG services (the intervention – updated to account for MBS services in metropolitan/regional and rural/remote locations) resulted in a lower cost per accurate diagnosis than in-laboratory Level 1 PSG (the comparator).

Table 14 Results of cost-minimisation analysis

Cost ($)	Initial testing	Repeat testing (1)	Repeat testing (2)	Total cost	Cost per diagnosis	Accurate diagnoses (%)	Cost per accurate diagnosis
DCAR 1712 PICO Set 1							
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**	**-645.29**
Resubmission (DCAR 1712.1)							
Intervention	868.16	74.14	2.62	944.92	2,362.30	0.99	2,390.99
Comparator	1,129.47	0.00	0.00	1,129.47	2,823.68	1.00	2,823.68
Difference (intervention – comparator)	**-261.31**	**74.14**	**2.62**	**-184.55**	**-461.38**	**-0.01**	**-432.69**

DCAR = Department Contracted Assessment Report.
Source: Table 45 of DCAR 1712.1.

Cost per accurate diagnosis was assessed by population and location (Table 15). All scenarios are cost saving compared to Level 1 PSG, with greater savings for testing in the metropolitan/regional locations.

Table 15 Results of cost-minimisation analysis weighted by populations

Population	Cost per accurate diagnosis ($) Intervention	Cost per accurate diagnosis ($) Comparator	Difference ($) (intervention – comparator)
Children (MBS Item AAAA)	2,347.25	2,823.68	-476.42
Adolescents (MBS Item BBBB)	2,259.58	2,823.68	-564.10
Children, MM 3-7 (MBS Items AAAA + CCCC)	2,652.80	2,823.68	-170.88
Adolescents, MM 3-7 (MBS Items BBBB + CCCC)	2,565.12	2,823.68	-258.56
Total	**2,390.99**	**2,823.68**	**-432.69**

MM = Modified Monash category.
Source: Table 46 of DCAR 1712.1.

In one-way sensitivity analyses, the intervention was cost-saving under all analyses with the exception of where the lower limit of test sensitivity for Level 2 PSG was applied (0.29) rather than the point estimate (1.00 in the base case analysis), resulting in the intervention cost being higher than the comparator cost by $531.86 (Table 16 and Table 17).

Table 16 Key drivers of the model

Description	Method/Value	Impact Base case: -$432.69difference in cost per accurate diagnosis
Sensitivity of Level 2 PSG	Estimated as 1.00 in the base case analysis, with lower limit of 0.29 tested in a sensitivity analysis.	*Moderate, favours comparator* *Use of lower sensitivity value increased the cost per accurate diagnosis to $531.86 more expensive for the intervention, relative to the comparator*
Variation in expected prevalence	Varied from 20 to 60% in a sensitivity analysis, 40% for the base case.	*High, favours intervention* *Use of lower prevalence value (20%) decreased the cost per accurate diagnosis to $845.94 less expensive for the intervention versus the comparator*

PSG = polysomnography.

Table 17 Key sensitivity analyses

Sensitivity analysis scenario	Cost per accurate diagnosis ($) (intervention)	Cost per accurate diagnosis ($) (comparator)	Difference ($) (intervention – comparator)
Base case analysis	**2,390.99**	**2,823.68**	**-432.69**
Application proposed MBS items/fees	2,391.77	2,823.68	-431.90
Level 2 PSG in children only (aged 3 to 11 years, inclusive)[a]	2,407.38	2,823.68	-416.29
Level 2 PSG in adolescents only (aged 12 to 17 years, inclusive)[a]	2,319.71	2,823.68	-503.97
Lower limit of Level 2 PSG test sensitivity 0.29 (base case 1.00)	3,355.54	2,823.68	531.86
Lower limit of Level 2 PSG test specificity 0.88 (base case 0.98)	2,545.58	2,823.68	-278.10
Initial test failure 20% (base case 10%)[b]	2,585.21	2,823.68	-238.46
Prevalence 20% (base case 40%)	4,801.42	5,647.35	-845.94
Prevalence 60% (base case 40%)	1,587.57	1,882.45	-294.89
'Any OSA' as treatment threshold (sensitivity 93%, specificity 97%, prevalence 60%)	1,664.76	1,882.45	-217.69
Lower estimate of % rural/remote location (**12%**, base case 20%)[c]	**2,367.52**	**2,823.68**	**-456.15**
Upper estimate of % rural/remote location (36%, base case 20%)[d]	2,440.85	2,823.68	-382.82
Inclusion of OOP costs (gap for specialist fees and travel costs)	2,466.03	3,182.49	-716.45

OOP = out-of-pocket; OSA = obstructive sleep apnoea; PSG = polysomnography.
a. The base case scenario assumes 18.7% adolescents and 81.3% children, with different costs for these 2 age groups. The sensitivity analyses test the impact of this assumption. (The base case in DCAR 1712 assumed 18.5% adolescents and 81.5% children).
b. The intervention (but not comparator) cost changes because the retesting for failure of initial Level 2 PSG testing is assumed to be 50% Level 1 and 50% Level 2 studies in the intervention group.
c. Lower estimate calculated from departmental data for MBS claims for paediatric Level 1 PSG (MBS items 12210 and 12213) by MM category, 2018-2024.
d. Upper estimate of 36% calculated using updated (2022-23) data for admitted patient care from the Australian Institute of Health and Welfare.
Source: Table 47 of DCAR 1712.1.

14. Financial/budgetary impacts

A market-share approach was taken to estimate the use of paediatric Level 2 PSG in Australia. However, the large prevalent population could lead to growth in uptake of paediatric sleep studies if clinical pathways and access to services were to change.

The market share approach is based on the number of claims for existing Level 1 PSG items. The proposed service is expected to lead to both the replacement of a proportion of Level 1 PSG services, estimated from waitlist data provided in the application at 34.5%, and the growth in demand for Level 2 PSG services independently of Level 1.

The financial implications to the MBS resulting from the proposed listing of out-of-laboratory Level 2 PSG services (but based on the Department proposed item descriptors) are summarised in Table 18 for children and Table 19 for adolescents. The net financial impact to the MBS is estimated to be cost saving initially but leads to additional cost to the MBS from the second year 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 saving. The costs are predominately attributable to use of the items for children rather than adolescents.

Table 18 Net financial implications to the MBS of Level 2 PSG in children (3-11 years)

Parameter	FY 2025-26	FY 2026-27	FY 2027-28	FY 2028-29	FY 2029-30	FY 2030-31
Estimated use and cost of the proposed health technology						
Number of proposed Level 2 services (metropolitan/regional)	2026	2330	2679	3081	3543	4075
Number of proposed Level 2 services (rural/ remote)	506	582	670	770	886	1019
Cost to the MBS (metropolitan/regional)	$873,089	$1,004,053	$1,154,661	$1,327,860	$1,527,039	$1,756,094
Cost to the MBS (rural/ remote)	$267,782	$307,949	$354,141	$407,263	$468,352	$538,605
Change in use and cost of other health technologies						
Substitution of Level 1 services	-2,279	-2,393	-2,513	-2,638	-2,770	-2,909
Saving to the MBS	-$1,457,965	-$1,530,863	-$1,607,406	-$1,687,777	-$1,772,165	-$1,860,774
Additional testing due to failed Level 2 tests [a]						
Number of first test failures	253	291	335	385	443	509
Number of second test failures	8	9	10	12	13	15
Total cost to the MBS of test failures	$142,901	$164,337	$188,987	$217,335	$249,936	$287,426
Additional consultations with sleep physician						
Number of new (not substituted) services	253	519	836	1213	1659	2185

Parameter	FY 2025-26	FY 2026-27	FY 2027-28	FY 2028-29	FY 2029-30	FY 2030-31
Total cost to the MBS of consultant physician attendance	$56,347	$115,512	$186,086	$269,910	$369,102	$486,109
Net financial impact to the MBS	**-$117,845**	**$60,987**	**$276,469**	**$534,591**	**$842,263**	**$1,207,460**

FY = financial year; MBS = Medicare Benefits Schedule; PSG = polysomnography.
a. It is assumed that 50% of Level 2 test failures repeat a Level 2 PSG and 50% have a Level 1 PSG, consistent with Section 3.
Source: Table 49 of DCAR 1712.1.

Table 19 Net financial implications to the MBS of Level 2 PSG in adolescents (12-17 years)

Parameter	FY 2025-26	FY 2026-27	FY 2027-28	FY 2028-29	FY 2029-30	FY 2030-31
Estimated use and cost of the proposed health technology						
Number of proposed Level 2 services (metropolitan/regional)	467	537	618	711	817	940
Number of proposed Level 2 services (rural/ remote)	117	134	154	178	204	235
Cost to the MBS (metropolitan/regional)	$188,240	$216,476	$248,947	$286,290	$329,233	$378,618
Cost to the MBS (rural/remote)	$58,478	$67,249	$77,337	$88,937	$102,278	$117,619
Change in use and cost of other health technologies						
Substitution of Level 1 services	-526	-552	-579	-608	-639	-671
Saving to the MBS	-$302,880	-$318,024	-$333,925	-$350,622	-$368,153	-$386,560
Additional testing due to failed Level 2 tests [a]						
Number of first test failures	58	67	77	89	102	117
Number of second test failures	2	2	2	3	3	4
Total cost to the MBS of test failures	$30,336	$34,886	$40,119	$46,137	$53,058	$61,016
Additional consultations with sleep physician						
Number of new (not substituted) services	58	120	193	280	383	504
Total cost to the MBS of consultant physician attendance	$12,994	$26,638	$42,914	$62,245	$85,120	$112,103
Net financial impact to the MBS	**-$12,832**	**$27,226**	**$75,392**	**$132,987**	**$201,535**	**$282,796**

FY = financial year; MBS = Medicare Benefits Schedule; PSG = polysomnography.
a. It is assumed that 50% of Level 2 test failures repeat a Level 2 PSG and 50% have a Level 1 PSG, consistent with Section 3.
Source: Table 50 of DCAR 1712.1.

Table 20 Net financial implications to the MBS of Level 2 PSG in children and adolescents (3-17 years)

Parameter	FY 2025-26	FY 2026-27	FY 2027-28	FY 2028-29	FY 2029-30	FY 2030-31
Net financial impact for children (3-11 years)						
Number of proposed Level 2 services	2,532	2,912	3,349	3,852	4,429	5,094
Net financial impact	-$117,845	$60,987	$276,469	$534,591	$842,263	$1,207,460
Net financial impact for adolescents (12-17 years)						
Number of proposed Level 2 services	584	672	772	888	1,021	1,175
Net financial impact	-$12,832	$27,226	$75,392	$132,987	$201,535	$282,796
Net financial impact for all paediatrics (3-17 years)						
Number of proposed Level 2 services	3,116	3,584	4,122	4,740	5,451	6,268
Net financial impact	-$130,677	$88,213	$351,861	$667,578	$1,043,798	$1,490,257

FY = financial year; MBS = Medicare Benefits Schedule; PSG = polysomnography.
Source: Table 51 of DCAR 1712.1.

15. Other relevant information

Nil.

16. Applicant comments on MSAC's Public Summary Document

The Australasian Sleep Association welcomes the decision to fund Level 2 (home-based) sleep studies for children and adolescents. This change will make timely, high-quality assessment of sleep-disordered breathing far more accessible across Australia. By complementing existing laboratory-based studies, this will help reduce wait times, lower travel and out-of-pocket costs, and make care easier for families—especially those in regional and remote areas and First Nations communities. Technician-supported home testing is child-friendly and clinically robust, enabling earlier diagnosis and treatment that can improve learning, behaviour, and overall health.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website