Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1631 – Home sleep apnoea test utilizing peripheral arterial tone

Applicant: **Itamar Medical Ltd**

Date of MSAC consideration: **MSAC 82nd Meeting, 29-30 July 2021**

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

1.   Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of home sleep apnoea test (HSAT) using peripheral arterial tone (PAT) for the diagnosis of obstructive sleep apnoea (OSA) was received from Itamar Medical by the Department of Health.

2.   MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support creation of a new MBS item for home sleep apnoea test utilising peripheral arterial tone (HSAT/PAT) for the diagnosis of OSA. MSAC advised that there was insufficient evidence to demonstrate non-inferior safety and effectiveness of HSAT/PAT compared to unattended or attended polysomnography (PSG) sleep studies. MSAC advised that issues with the economic model resulted in unacceptably uncertain cost-effectiveness, the proposed fees were inadequately justified, and the financial estimates were highly uncertain.

Consumer summary
Itamar Medical applied for public funding via the Medical Benefits Schedule (MBS) of home sleep apnoea tests using peripheral arterial tone (HSAT/PAT). Sleep apnoea tests are used to diagnose obstructive sleep apnoea.
Obstructive sleep apnoea is where the airway is partially or completely blocked during sleep, which can cause breathing to reduce or stop.
Polysomnography (PSG) is a type of sleep study that uses electrodes and sensors to continuously measure multiple body functions such as brain activity, heart rhythm and breathing. It can be done at a sleep clinic with overnight supervision by a sleep physician, or at a person's home with the help of a sleep scientist to set up the test only. HSAT/PAT uses a device that looks like and is attached like a watch and a chest probe to measure some

Consumer summary

of the body functions measured by PSG, such as heart rate, body movement and snoring sound level. The device can be posted to a person's home and be used without a sleep physician coming to the person's home but requires the person to use a smartphone with internet connection to send the test data to a sleep physician.

MSAC accepted there was a place for HSAT/PAT in diagnosis of obstructive sleep apnoea but did not consider there was enough information to demonstrate that HSAT/PAT is as safe and effective as PSG. MSAC also considered that the proposed fees for the device were not explained sufficiently.

MSAC's advice to the Commonwealth Minister for Health

MSAC did not support creating a new MBS item for HSAT/PAT. MSAC was not convinced that HSAT/PAT is as safe and as effective as PSG and was uncertain whether HSAT/PAT was good value for money.

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

MSAC noted this application requested MBS listing of HSAT/PAT for the diagnosis of OSA. The specific HSAT/PAT in the Applicant Developed Assessment Report (ADAR) uses a patient-worn device (WatchPAT) that measures up to seven parameters. The target population is the same population that is eligible for MBS funded unattended (home-based) Level 2 PSG (primary comparator) or a laboratory-based Level 1 PSG (secondary comparator and reference standard).

MSAC noted that HSAT/PAT devices do not measure the same parameters as Level 2 PSG, such as airflow, continuous electromyography (EMG), continuous electrocardiogram (ECG), continuous electroencephalogram (EEG) or electro-oculography (EOG). As such, HSAT/PAT is not eligible to be claimed under MBS item 12250 for Level 2 PSG. MSAC noted specific mandatory training and accreditation should be required, and that the HSAT/PAT generates an automated report that can be manually reviewed and scored[1] by an accredited sleep technologist or sleep physician and that any further treatment should be determined by a sleep physician.

MSAC noted the consultation feedback received was mostly supportive of HSAT/PAT, noting benefits of HSAT/PAT in the diagnosis of OSA include ease of use and potential to improve access in remote areas. MSAC noted that the HSAT/PAT device can be posted to a patient's home with 24-hour support, which could improve access for regional and remote patients, but that the single use device requires a smartphone and an internet connection. However, MSAC noted the claimed benefits of consumer convenience and improved access to be largely assumptions that were not based on real-world evidence.

MSAC noted the ADAR proposed two new MBS item numbers for HSAT/PAT: one for a single use device (with the same item fee as MBS item 12250), and one for a reusable device (with a fee of $30 less than MBS item 12250). MSAC noted the pre-MSAC response provided an updated breakdown of the proposed fees, clarified that the descriptor should specify epochs of 1 minute (not 20 minutes) and suggested new parameter criteria. MSAC noted Department advice that the MBS is intended to subsidise the professional service, with

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[1] Zhang et al. (20250) *Journal of Clinical Sleep Medicine*. 16(4):563-573.

consideration to time and complexity, as opposed to the cost of the device or consumables. MSAC noted Department advice that the fee for MBS item 12250 (Level 2 PSG) should reflect the cost of the professional service only, but also noted applicant advice that service providers consulted by the applicant, are not separately billing for the consumables used in such studies. MSAC considered that the applicant's fee breakdown did not provide sufficient justification for the sleep technologist or professional service components of the proposed fee relative to existing PSG studies.

MSAC noted there was limited, low quality evidence comparing HSAT/PAT with Level 2 PSG (primary comparator), which consisted of two cohort studies (O'Brien et al. 2012[2] and Zou et al. 2006[3]) with a high risk of bias. MSAC also noted the two cohort studies were highly selective in their patient populations (i.e. pregnant women and patients selected from a hypertension and diabetes database) and therefore, not representative of the proposed population. MSAC noted a larger evidence base (k=16) comparing HSAT/PAT with Level 1 PSG (secondary comparator) but that the HSAT/PAT device was used in a sleep laboratory setting, with attendance by a sleep technician. MSAC noted the pre-MSAC response reiterated claims that the performance of HSAT/PAT would not be enhanced when used in the laboratory compared to home. However, MSAC agreed with ESC and considered it was uncertain whether the results obtained in the Level 1 PSG studies for HSAT/PAT would accurately reflect results that would be obtained in clinical practice.

Regarding comparative safety, MSAC noted the studies comparing HSAT/PAT with Level 2 or Level 1 PSG did not directly assess safety outcomes. MSAC noted the pre-MSAC response reiterated that there were no safety outcomes included in the ratified PICO. However, MSAC was concerned that the potential harm with HSAT/PAT, through over-diagnosis or mis-diagnosis, over-treatment or psychosocial harms (for example, anxiety and labelling), had not been considered and addressed in the ADAR. Overall, MSAC considered there was insufficient evidence to demonstrate non-inferior safety of HSAT/PAT with either Level 2 or Level 1 PSG.

Regarding the assessment of the comparative efficacy of HSAT/PAT, MSAC noted that the ADAR only provided evidence on the comparative diagnostic performance of HSAT/PAT. Comparing the diagnostic accuracy of HSAT/PAT versus Level 2 PSG, MSAC noted that the apnoea hypopnoea index (AHI) correlation were good but inconsistent across the two studies (r=0.73 in O'Brien et al. 2012; r=0.90 in Zou et al. 2006). MSAC also noted that the HSAT/PAT failure rates ranged 0% to 9.6% depending on setting. Comparing the diagnostic accuracy of HSAT/PAT versus Level 1 PSG, MSAC noted the pre-MSAC response reiterated the reason for excluding the one contrasting study (Ioachimescu et al. 2020[4]) which stated that PAT-based testing showed high rates of diagnostic misclassification (30%–50%) when compared with Level 1 PSG. MSAC considered that including/excluding the Ioachimescu et al. (2020) from the AHI meta-analysis did not have much of an effect on the meta-analysed AHI correlation between HSAT/PAT and Level 1 PSG.

MSAC noted there was no evidence provided on the clinical utility of HSAT/PAT, or evidence relevant to therapeutic efficacy or therapeutic effectiveness. MSAC also noted that the ADAR had not provided evidence or discussion linking the results for the Level 2 PSG studies to the reference standard of Level 1 PSG. MSAC noted the pre-MSAC response, that these outcomes and comparisons were not specified in the ratified PICO. However, MSAC

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[2] O'Brien L, et al. (2012) *Journal of Clinical Sleep Medicine.* 8:287-294.
[3] Zou D, et al. (2006). *Sleep.* 29:367-374.
[4] Ioachimescu, O. C. et al. (2020) *Journal of Investigative Medicine*. 68(8):1370-1378.

considered the lack of direct evidence on the comparative effectiveness of HSAT/PAT in terms of health outcomes, in accordance with the MSAC guidelines, to a be an important limitation and as such the ADAR did not provide evidence that OSA diagnosis through HSAT/PAT will benefit patients, particularly in the setting of differential misclassification in both directions.

Overall, MSAC considered that the comparative evidence provided was insufficient to support the clinical claim that HSAT/PAT has non-inferior safety and effectiveness compared to Level 2 PSG and Level 1 PSG.

MSAC noted that the economic analysis presented in the ADAR was not a cost-minimisation analysis, but instead a financial estimate for the overall health system over 5 years, with each year presented separately. MSAC noted the claimed cost savings are largely driven by reduced hospital costs through substitution of Level 1 PSG with HSAT/PAT and agreed with ESC that substitution of Level 1 PSG with HSAT/PAT was highly uncertain. MSAC noted ESC raised several other issues with the economic evaluation. MSAC noted the pre-MSAC response reiterated the basis for assuming that HSAT/PAT had the same failure rate as Level 2 PSG and suggested the failure rate of HSAT/PAT is 1.76% based on recent unpublished real-world usage in regional Australia. MSAC also noted that the cost per patient used in the analysis was based on incorrect MBS items, which the pre-MSAC response argued were applied equally to Level 1 and Level 2 PSG and therefore would not change the overall results. MSAC agreed with ESC concerns that the economic analysis had not taken into consideration that HSAT/PAT has high sensitivity and poor specificity, leading to false positives that result in subsequent investment in treatment. Overall, MSAC considered the economic analysis and reported cost-savings of HSAT/PAT to be highly uncertain.

MSAC noted the financial estimates appeared to be a market share approach with direct substitution of current Level 2 and Level 1 PSG. MSAC noted the estimated financial savings were largely driven by reduced costs through substitution of Level 1 PSG with HSAT/PAT (and the lower requested price for the reusable device). However, MSAC noted the financial estimates did not include eligibility, rate of uptake or determination of costs. MSAC considered the estimated uptake of HSAT/PAT to be highly uncertain. MSAC agreed with ESC that HSAT/PAT is likely to increase the overall market as it is easier to administer. MSAC agreed with ESC that estimated use of Level 1 PSG substitution is uncertain and likely an over-estimate. MSAC noted the pre-MSAC response reiterated claims regarding HSAT/PAT substitution of Level 1 PSG. However, MSAC agreed with ESC that HSAT/PAT substitution of Level 1 PSG to be highly uncertain as there was insufficient information to adequately justify which (and how many) patients who are unsuitable for an unattended (Level 2) PSG and require a Level 1 PSG could swap to HSAT/PAT. Overall, MSAC considered the financial estimates to be highly uncertain.

MSAC considered that there may be a place for HSAT/PAT in the diagnosis of OSA. MSAC was concerned that including this test on the MBS would likely expand testing, which could result in overdiagnosis of OSA and increased sales of associated devices to treat OSA. MSAC was uncertain if listing HSAT/PAT on the MBS would lead to changed clinical management or improved health outcomes, noting no evidence to suggest this was presented in the ADAR. MSAC suggested referring the application to the Medical Research Future Fund (MRFF).

MSAC considered that any resubmission would need higher-quality comparative evidence for HSAT/PAT, including the clinical utility of HSAT/PAT in each proposed test setting, along with revised economic and financial analyses (Table 1).

Table 1 Requirements for a resubmission

Item	MSAC advice
Clinical evidence	Provide higher quality (direct) evidence to demonstrate non-inferiority of HSAT/PAT compared to the main comparator in accordance with MSAC guidelines for investigative technologies, i.e. should also include assessment of the clinical utility of HSAT/PAT.
Proposed fee	The proposed MBS fee for HSAT/PAT should cover the professional service only and appropriate justification that the proposed fee is commensurate with the technologist or professional service should be provided.
Substitution of Level 1 PSG	Provide information to adequately justify which (and how many) patients who are unsuitable for an unattended (Level 2) PSG and require a Level 1 PSG could swap to HSAT/PAT.
Economic analysis	Present a revised economic analysis in accordance with MSAC guidelines that addresses the concerns raised including: • revised and appropriately justified costs including revised proposed MBS fee • re-testing using Level 1 PSG based on HSAT/PAT failure rates in the home-based setting • false positives (due to high sensitivity and poor specificity of HSAT/PAT) leading to subsequent need for re-testing or investment in treatment.
Financial estimates	Present a revised financial analysis in accordance with MSAC guidelines that addresses the concerns raised including: • eligibility • rate of uptake and including revised HSAT/PAT uptake estimates that take into consideration the potential for HSAT/PAT to grow the market, the decreasing utilisation of Level 1 PSG and unlikely potential for HSAT/PAT to substitute Level 1 PSG • determination of costs, including corrected MBS items • re-testing using Level 1 PSG based on HSAT/PAT failure rates in the home-based setting.

4.   Background

This is the first submission (Applicant Developed Assessment Report [ADAR]) for HSAT/PAT for diagnosis of OSA (MSAC 1631).

Diagnostic sleep studies are categorised into for types:
- Level 1 (PSG),
- Level 2 (unattended PSG),
- Level 3 (unattended limited channel ≥ 4 parameters) and
- Level 4 (unattended limited channel 1-2 parameters).

HSAT/PAT are categorised as a Level 3 sleep study in the 2017 Australasian Sleep Association guidelines for sleep studies in adults[5]. Currently, MBS funding for diagnostic sleep studies is restricted to Level 1 and Level 2 sleep studies.

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[5] Douglas J, et al. (2017) Guidelines for sleep studies in adults e a position statement of the Australasian Sleep Association. *Sleep Medicine*. 36:S2-S22.

In March 2010, MSAC considered application 1130 for unattended sleep studies. At that time MSAC supported MBS listing of adult Level 2 sleep studies on a referred basis because, with seven parameters studied[6], it was considered safe and effective (in terms of diagnostic accuracy) and still likely to be cost saving compared to Level 1 sleep studies. MSAC did not support public funding for Levels 3 and 4 sleep studies and the use of unattended sleep studies in paediatric and reassessment settings, due to concerns about poor diagnostic performance resulting in unnecessary and potentially harmful interventions such as adenotonsillectomy based on false positive findings in the paediatric setting and the uncertain effectiveness of this service for reassessment in all settings (MSAC application 1130, Public Summary Document [PSD], p5/6).

5. Prerequisites to implementation of any funding advice

The applicant advised that their HSAT/PAT device, the WatchPat, was registered on the Australian Register of Therapeutic Goods (ARTG) on 18 February 2013. A competitor HSAT device, the NightOwl, is also listed on the ARTG (Table 2). The pre-MSAC response highlighted the NightOwl measures photoplethysmography rather than PAT.

Table 2 HSAT/PAT ARTG listing

ARTG no.	Manufacturer	Product category / GMDN	Intended purpose
206199	Itamar Medical Ltd	Medical device class IIA 33843 - sleep assessment device	To be used as a diagnostic tool in the medical management of sleep-related breathing disorders. Can be used in the diagnosis of myocardial ischemia and endothelium dysfunctions. To be worn on the wrist by the patient at home while they sleep along with a non-invasive finger mounted pneumo-optical probe to measure the peripheral arterial tonometry (PAT) signal. In addition to the PAT signal, oxygen saturation, actigraphy (body movement), pulse rate, body position and snoring (dB) are also recorded and stored on the device from which the recorded signals can be downloaded to a computer for automatic analysis and reporting utilising proprietary algorithms. Can provide analysis of respiratory disturbance, apnoea-hypopnoea, endothelial function, oxygen desaturation, REM/NREM sleep stages, light/deep sleep stages, sleep/wake states, heart rate, oxygen saturation level, body position and snoring
319834	Ectosense NV	Medical device class I 12391 Physiology/motion recording wristband	The NightOwl Sensor is intended to be used for the continuous recording of a patient's pulse waveform (also known as photoplethysmography, or 'PPG') and motion during sleep or resting, in both the clinical and home environment. The sensor can be worn either on the forehead or finger by adults or children aged 13 and over, without requiring direct supervision by a healthcare provider.
320061	Ectosense NV	Medical device class II 42238 Polysomnography device application software	The NightOwl Software is a computer program (software) intended for physiological signal retrieval, visualisation, report generation, analysis and interpretation for the area of direct diagnosis and monitoring of obstructive sleep apnoea.

Source: ARTG website, accessed 11/6/2021
Abbreviations: GDMN=global medical device nomenclature; HSAT=home sleep apnoea test; PAT=peripheral arterial tone; PPG= photoplethysmography; REM=rapid eye movement; nREM=non rapid eye movement

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[6] Minimum parameters to be measured in a Level 2 PSG study as per MBS item 12250: Level 2 PSG includes airflow, continuous electromyography (EMG), continuous electrocardiogram (ECG), continuous electroencephalogram (EEG), electro-oculography (EOG), oxygen saturation and respiratory effort

6.   Proposal for public funding

HSAT/PAT devices do not measure the same parameters as Level 2 PSG and therefore sleep studies conducted using HSAT/PAT devices are not eligible to be claimed under the MBS item for Level 2 unattended sleep studies (MBS item 12250).

MSAC application 1631 initially proposed amending MBS item 12250. However, in response to PASC advice, the ADAR proposed creation of two new MBS items, one for conducting a HSAT/PAT sleep study using a single use HSAT/PAT device and one for conducting a HSAT/PAT sleep study using a reusable HSAT/PAT device. The proposed item descriptors for the HSAT/PAT sleep study using a single use and reusable HSAT/PAT device are the same except for the fee, with the single use HSAT/PAT item having the same item fee as MBS item 12250, and the re-usable HSAT/PAT item having a proposed fee of $30.00 less than MBS item 12250 (Table 3).

The commentary noted that the ADAR did not provided a transparent breakdown of the cost of the device, consumables and service, as such it is unclear how much of the proposed MBS fee for HSAT/PAT is attributable to the device. The pre-MSAC response provided a tabular breakdown of the proposed fees for the re-usable and single use HSAT/PAT, which assumed the professional services would be similar for a Level 2 PSG and HSAT/PAT but that sleep technologists time would reduce from 2 hrs for a Level 2 PSG to 0.5hr for HSAT/PAT. The pre-MSAC response stated that the single use WatchPAT device costs **redacted** and the consumables for the reusable WatchPAT device cost **redacted**.

Table 3 Proposed MBS item descriptors - single use HSAT/PAT and re-usable HSAT/PAT

Category 2 – Diagnostic procedures and investigations
MBS item #### (single use device)   MBS item #### (re-usable device)
Overnight investigation of sleep for a period of 6-8 hours of a patient aged 18 years or more to confirm diagnosis of obstructive sleep apnoea by use of a single use PAT device if:
(a) either:
(i) the patient has been referred by a medical practitioner to a qualified sleep medicine practitioner or a consultant respiratory physician who has determined that the patient has a high probability for symptomatic, moderate to severe obstructive sleep apnoea based on a STOP Bang score of 3[a] or more, an OSA50 score of 5 or more or a high-risk score on the Berlin Questionnaire, and an Epworth Sleepiness Scale score of 8 or more; or
(ii) following professional attendance on the patient (either face to face or by video conference) by a qualified sleep medicine practitioner or a consultant respiratory physician, the qualified sleep medicine practitioner or consultant respiratory physician determines that investigation is necessary to confirm the diagnosis of obstructive sleep apnoea; and
(b) during a period of sleep, there is continuous monitoring and recording, performed in accordance with current professional guidelines, of the following measures:
(i) peripheral arterial tone (PAT).
(ii) heart rate.
(iii) oxygen saturation.
(iv) wrist-worn actigraphy.
(v) chest motion.
(vi) snoring level; and
(vii) body position
(c) the investigation is performed under the supervision of a qualified sleep medicine practitioner; and
(d) either:
(i) the equipment is provided to a patient by the sleep technician.
(ii) a sleep technician provides the patient with written instructions on how to apply the equipment and upload the results for assessment by a qualified sleep technician and/or medicine practitioner
e) polygraphic records are:
(i) analysed (for assessment of sleep stage, sympathetic arousals respiratory events and cardiac abnormalities) with manual scoring, or manual correction of computerised scoring in epochs of not more than 20 minutes; and
(ii) stored for interpretation and preparation of report; and
(f) interpretation and preparation of a permanent report is provided by a qualified sleep medicine practitioner with personal direct review of raw data from the original recording of polygraphic data from the patient; and
(g) the investigation is not provided to the patient on the same occasion that a service mentioned in any of items 11000, 11003, 11004, 11005, 11503, 11704, 11705, 11707, 11714, 11716, 11717, 11723, 11735, 12203 and 12250 is provided to the patient
Applicable only once in any 12- month period
(See para-DN.1.17 of explanatory notes to this Category)
MBS Fee (single use device): $345.75 Benefit: 75% = $259.35 Benefit 85% = $293.90 MBS Fee (re-usable device): $315.75 Benefit: 75% = $236.809 Benefit 85% = $268.40

Source: Table 2, p14 of the Commentary
[a] The STOP Bang level was amended to 3 in March 2021, see MBS online:
   http://www9.health.gov.au/mbs/search.cfm?q=12250&Submit=&sopt=I

Table 4 provides a comparison of the parameters in the ADAR proposed MBS items for HSAT/PAT, parameters proposed in the pre-MSAC response and the parameters specified in MBS item 12250 (Level 2 sleep study).

Table 4 Measures monitored and recorded in proposed MBS items for HSAT/PAT and in MBS item 12250

ADAR - HSAT/PAT single use and re-usable proposed items	Pre-MSAC response - HSAT/PAT single use and re-usable proposed items	MBS item 12250
(i) Peripheral arterial tone (PAT)	(i) AHI for the whole night, AHI in REM and AHI in Non-REM	(ii) Airflow
(ii) Heart rate	(iii) ODI for the whole night, ODI in REM and ODI Non-REM	(iv) Continuous EMG
(iii) Oxygen saturation	(v) AHI for Central Sleep Apnea	(vi) Continuous ECG
(iv) Wrist-worn actigraphy	(vii) Snoring volume	(viii) Continuous EEG
(v) Chest motion	(ix) Heart Rate	(x) EOG
(vi) Snoring level	(xi) AHI per Body position	(xii) Oxygen saturation
(vii) Body position	(xiii) Chest motion	(xiv) Respiratory effort
	(xv) Estimated sleep time and REM time.	
	(xvi) Sleep latency and number of wakes	

Source: Table 3, p15 of the Commentary with pre-MSAC response added
Abbreviations: ECG=electrocardiogram; EEG=electroencephalography; EMG=electromyogram; EOG=electrooculogram; HSAT=home sleep apnoea test; PAT=peripheral arterial tone

7.   Summary of public consultation feedback/consumer Issues

Consultation feedback was received from four organisations: the Australasian Sleep Association (ASA), the Australian Society of Otolaryngology Head and Neck Surgery (ASOHNS), the Royal Australian College of General Practitioners (RACGP) and Ectosense *nv* (medical device manufacturer).

The ASA noted that the device proposed for the service may be easier for patients to use than the Level 2 devices currently available and that it has a role in the diagnosis of OSA. They considered that a sleep physician should be involved as another service offered before/after delivery of this service to assist with interpreting, reporting and following up. They however strongly disagreed with the comparator, and considered that the device is not equivalent to a Level 2 study as it does not continuously and directly measure all the signals described in MBS item 12250. They supported the service otherwise, but suggested that it could be more suitable as a Level 3 study for which there is currently no MBS item.

The ASOHNS considered a benefit for the service is that it is almost as accurate as other existing sleep studies and that the cost is significantly less. They suggested that assessment by a doctor before/after the service would be beneficial.

The RACGP submitted a letter as part of feedback with mixed support. They outlined some concerns with the test such as, it does not specifically measure respiration effort. They considered that more real-world evidence should be sought on how the test performs in the homes of general practice patients before inclusion of the service on the MBS. They noted that it may have a place in care, especially in remote areas where there is limited access to specialised sleep laboratories however, "*whilst there is the potential benefits of improved access, this must be balanced against its reliability in real world settings*". The RACGP considered that there is risk of over diagnosis of OSA as measured by PSG or other sleep study devices. They also noted that there are commercial implications and that direct to

consumer advertising of sleep studies puts pressure on GPs to provide referrals when requested by patients.

Feedback was also received from a manufacturer of a competitor product to WatchPAT based on PAT. The response was in support of the service being included on the MBS especially for multi-night testing, but was in strong disagreement with a number of aspects of the application such as the applicants definition of PAT, the stated comparator, the clinical claim, the proposed MBS item descriptor, and the fee proposed.

8. Proposed intervention's place in clinical management

Description of Proposed Intervention
The proposed intervention, HSAT utilising PAT (HSAT/PAT), is a patient-worn device that is intended for use in the home setting while the patient sleeps for the diagnosis of OSA. The applicant's HSAT/PAT device, the WatchPAT, is attached at the patients' chest, wrist and finger, and measures seven parameters: PAT signal, heart rate, oximetry, actigraphy (body movement), body position, snoring sound level, and chest motion. The WatchPat can report sleep stages (light, deep, and rapid eye movement sleep), apnoea hypopnoea index, oxygen desaturation index and other indices for the purpose of diagnosing obstructive sleep apnoea.

Description of Medical Condition
The target population are people aged 18 or over who have a high probability of having moderate to severe OSA. Sleep apnoea is a common sleep-related breathing disorder. The most prevalent type of sleep apnoea is OSA, which is characterized by a narrowing of the upper airway that impairs normal ventilation during sleep, resulting in repeated reversible blood oxygen desaturation and fragmented sleep.

The clinical management algorithm and the proposed place of HSAT/PAT for diagnosis of moderate to severe OSA is presented in Figure 1.

The algorithm indicates HSAT/PAT can substitute Level 2 PSG and also substitute Level 1 PSG in patients who are unsuitable for a Level 2 PSG. The ADAR stated that patients who have a physical disability, cognitive impairment difficulty communicating, have a language barrier, have mobility problems or other physical disability; or patients for whom it is inconvenient or expensive to travel to a sleep laboratory may substitute HSAT/PAT for a Level 1 sleep study. However, the commentary noted that the ADAR did not provide any information on the type of degree of cognitive impairment, and how it could be ascertained that a patient with cognitive impairment would appropriately apply the device. Also, as use of HSAT/PAT still requires instruction, it is not clear how it may be suitable for patients who have difficulty communicating or have a language barrier. Therefore, the ADAR did not adequately justified how patients who are unsuitable for a Level 2 sleep study and would require Level 1 PSG would be able to use HSAT/PAT.

Figure 1 Proposed clinical management algorithm for diagnosis of moderate to severe OSA
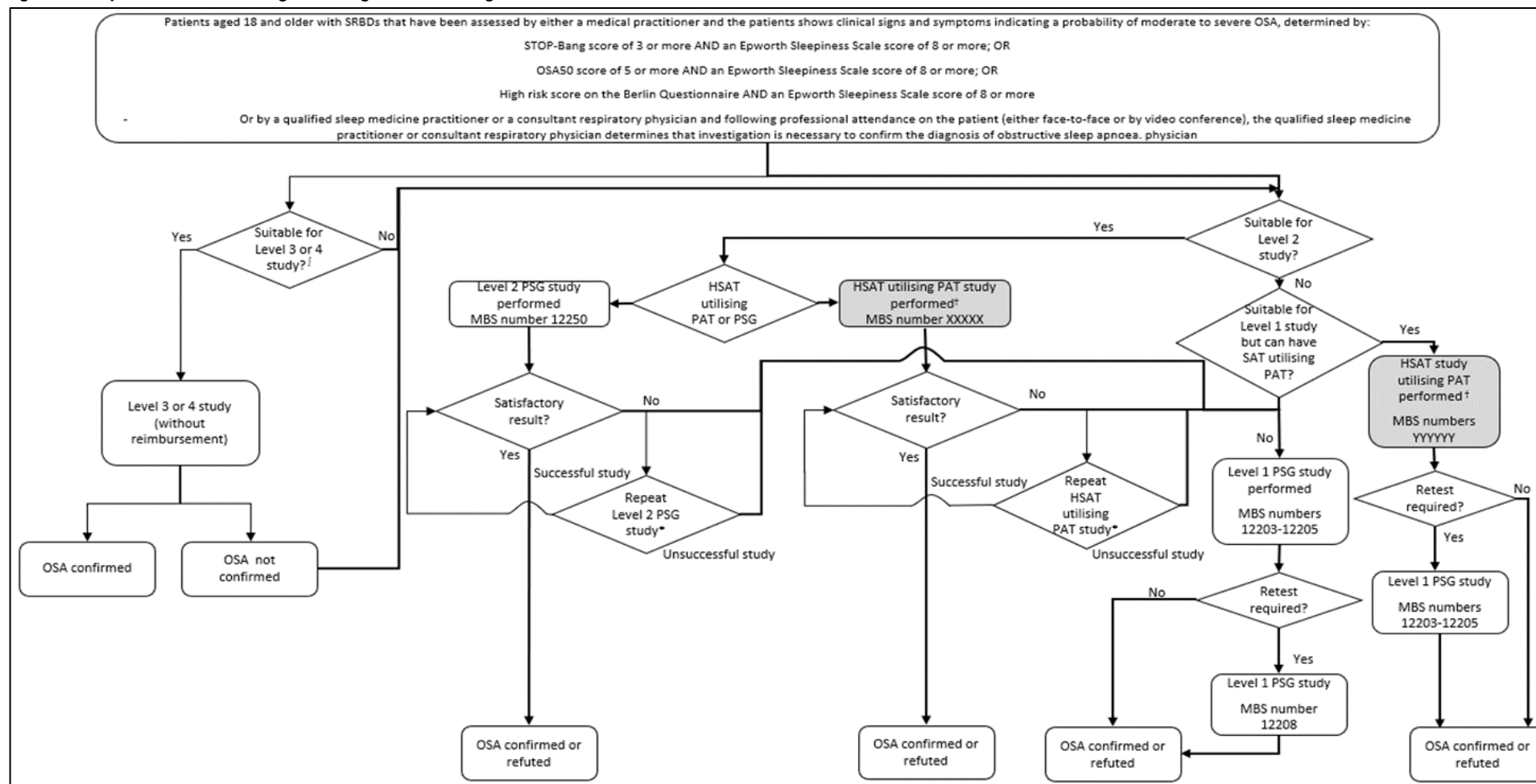
Source: Figure 8, p52 of the ADAR, adapted from Douglas (2017) Figure 1 p4
Abbreviations: HSAT=home sleep apnoea test; MBS=Medicare Benefits Schedule; OSA=obstructive sleep apnoea; PAT=peripheral arterial tone; PSG=polysomnograph

9. Comparator

Consistent with the PICO Confirmation, the main comparator presented in the ADAR is Level 2 PSG conducted at home.

The secondary comparator is Level 1 PSG, which are performed in a sleep laboratory with continuous supervision of a sleep technician. These tests may be conducted in a public or private hospital or a sleep clinic. The commentary noted that the 2017 Australasian Sleep Association guidelines for sleep studies in adults[7] identify Level 1 PSG as the reference standard.

The relevant MBS items for the comparators are:
- MBS item 12250 for unattended polysomnography diagnostic sleep study (Level 2)
- MBS item 12203 for attended/in-laboratory polysomnography diagnostic sleep study (Level 1).

The commentary noted that MBS items 12204 and 12207, which are also for attended attended/in-laboratory polysomnography diagnostic sleep study but are not relevant as these items are not intended for primary diagnosis of OSA.

10. Comparative safety

The ADAR included two studies comparing HSAT/PAT and Level 2 PSG (main comparator), along with 16 studies comparing HSAT/PAT and Level 1 PSG (secondary comparator). All selected studies were for assessment of the accuracy of HSAT/PAT. The commentary noted that the ADAR did not provided any evidence linking Level 1 and Level 2 PSG, and did not provide other types of evidence as described in the MSAC Investigative Technical Guidelines 2017 (i.e. prognostic evidence, comparative clinical validity, and therapeutic effectiveness).

A summary of the evidence used in the ADAR is provided in Table 5.

Table 5 Key features of the included evidence

Study	N	Design	Risk of bias[a]	Patient population	Key outcomes	Included in meta-analysis
Main comparator: Level 2 PSG						
O'Brien 2012	31	Cohort study with simultaneous application; one night; home-based	*High*	Pregnant women	AHI, RDI: sensitivity, specificity, PPV, NPV	No
Zou 2006	98	Cohort study with simultaneous application; one night; home-based	*High*	Selected from a hypertension and diabetes database	AHI, RDI, ODI: correlation	No
Secondary comparator: Level 1 PSG						
Ayas 2003	30	Cohort study with simultaneous application; sleep lab setting	Low	Adults with and without suspected OSA	AHI: correlation	Yes
Bar 2003	102	Cohort study with simultaneous application; sleep lab setting	Low	66 adults with suspected OSA and 33 healthy volunteers	RDI: correlation	Yes

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[7] Douglas JA, Chai-Coetzer CL, McEvoy D, Naughton MT et al. Guidelines for sleep studies in adults – a position statement of the Australasian Sleep Association. *Sleep Medicine* 2017; 36: S2-S22.

Study	N	Design	Risk of bias[a]	Patient population	Key outcomes	Included in meta-analysis
Choi 2010	27	Cohort study with sleep lab setting for PSG and one month later hospital-based setting for HSAT/PAT	*Unclear*	Adults with suspected OSA	AHI, LSAT: correlation	Yes
Gan 2017	20	Cohort study with simultaneous application; hospital sleep lab setting	Unclear	Adults with suspected OSA	AHI: correlation, sensitivity, specificity	Yes
Garg 2014	75	Randomised crossover study with sleep lab PSG and simultaneous sleep lab HSAT/PAT and home HSAT/PAT within 4 days of each other	Unclear	Adults at high risk of OSA	AHI: correlation, sensitivity, specificity, PPV, NPV	Yes
Hedner 2004	228	Cohort study with simultaneous application; hospital sleep lab setting for 2 cohorts and home setting for 1 cohort	Unclear	Adults with suspected OSA and normal volunteers	RDI: sensitivity, specificity, agreement	No
Ioachimescu 2020	500	Cohort study with simultaneous application; sleep lab setting	Low	Adults with suspected OSA	AHI: correlation	Yes
Kasai 2020	120	Cohort study with simultaneous application; hospital sleep lab setting	Low	Adults with suspected SDB	AHI: correlation, sensitivity, specificity	Yes
Körkuyu 2015	30	Cohort study with simultaneous application; hospital sleep lab setting	Low	Adults with preliminary OSA diagnosis	AHI, ODI: correlation	Yes
Onder 2012	56	Cohort study with simultaneous application; sleep lab setting	Low	Adults with suspected OSA	AHI: correlation and impact of age	Yes
Pang 2007	37	Cohort study with simultaneous application; sleep lab setting	Low	Adults with suspected OSA	AHI: correlation, sensitivity, specificity	Yes
Pillar 2020	84	Cohort study with simultaneous application; sleep lab setting	Low	Adults with suspected SDB with and without cardiac disorders	AHI: correlation, sensitivity, specificity for CSA	Yes
Pittman 2004	30	Cohort study with simultaneous application; sleep lab setting, Also HSAT/PAT in home setting with random order for lab and home testing	Unclear	Adults with suspected OSA	AHI, ODI: sensitivity, specificity, agreement, PPV, NPV	Yes
Weimin 2013	28	Cohort study with simultaneous application; hospital sleep lab setting	Unclear	Adults with suspected OSA	AHI: correlation, sensitivity, specificity, PPV, NPV	Yes
Yuceege 2013	85	Cohort study with simultaneous application; sleep lab setting (daytime)	Low	Night-time bus drivers	RDI, ODI: correlation, sensitivity and specificity for RDI	No
Yalamanchali 2013	909	Systematic review and meta-analysis of studies comparing lab PSG and HSAT/PAT	NR	NR	AHI, RDI, ODI: correlation	No

Source: Table 5, p19 of the Commentary
Abbreviations: AHI=apnoea hypopnoea index; CSA=central sleep apnoea; HSAT/PAT=home sleep apnoea test utilising peripheral arterial tone; LSAT=lowest oxygen saturation; NR=not reported; ODI=oxygen desaturation index; OSA=obstructive sleep apnoea; PSG=polysomnography; RDI=respiratory disturbance index; SDB=sleep disordered breathing
[a] Risk of bias as assessed during the evaluation is provided in *italics.*

The commentary considered the two studies comparing HSAT with Level 2 PSG (main comparator; O'Brien et al. 2012[8], Zou et al. 2006[9]) have limited applicability to the proposed patient population and the requested listing. The patients in the O'Brien et al. (2012) study were pregnant, which is not likely to be representative of the majority of the proposed patient population. In the Zou et al. (2006) study, patients were selected from a cohort of patients in a hypertension and diabetes database, and close to 25% of patients had either hypertension or diabetes, but results were provided for all patients combined. The studies selected for the secondary comparator also have limited applicability, as the majority included patients suspected of OSA, not those categorised with moderate to severe OSA. In addition, HSAT/PAT was applied in a sleep laboratory or hospital setting in all studies, and this is not representative of the proposed use of HSAT/PAT in the home setting. The pre-MSAC response reiterated claims that there were no tasks or adjustments for the sleep technician to perform during the studies and therefore claimed that the performance of HSAT/PAT would not be enhanced when used in the laboratory compared to home.

Regarding safety of HSAT/PAT, the ADAR stated that no known safety issues were identified for HSAT/PAT and MSAC previously concluded in MSAC application 1130 that Level 2 PSG are considered safe. On this basis, the ADAR claimed it is unlikely there would be a difference in the safety profile of the different sleep studies.

The commentary noted that the included studies generally did not directly assess safety outcomes and considered there remains potential for harm through over-diagnosis, over-treatment or psychosocial harms (e.g. anxiety, labelling)[10]. The ADAR did not provide any discussion of these potential harms. The pre-MSAC response reiterated claims that there are no known safety issues regarding HSAT/PAT and there were no safety outcomes included in the ratified PICO.

11. Comparative effectiveness

The ADAR did not consider direct effectiveness in terms of health outcomes and did not present any linked evidence to address therapeutic efficacy or effectiveness (health benefit from change in management). However, the ADAR provided evidence on test accuracy of HSAT/PAT compared with the Level 2 PSG and Level 1 PSG.

Accuracy of HSAT/PAT versus Level 2 PSG (main comparator)
The results from accuracy trials comparing HSAT/PAT with the main comparator, Level 2 PSG are presented in Table 6.

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[8] O'Brien L, et al. (2012) *Journal of Clinical Sleep Medicine.* 8:287-294.
[9] Zou D, et al. (2006). *Sleep.* 29:367-374.
[10] Jonas D, et al. (2017) Screening for Obstructive Sleep Apnoea in Adults: An Evidence Review for the U.S. Preventive Services Task Force: Agency for Healthcare Research and Quality (US); Report No: 14-05216-EF-1.

Table 6   Results of accuracy trials comparing HSAT/PAT and Level 2 PSG

Study	HSAT/PAT					Level 2 PSG	Correlation: HSAT/PAT and PSG
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Failure rate	Failure rate	
O'Brien 2012 (N=31)							
AHI=6.1	88%	86%			2/37	5/37	AHI: r=0.73
AHI ≥5	88%	87%	70%	95%	(5.4%)	(13.5%)	RDI: r=0.68
RDI ≥10	100%	81%	50%	110%			
Zou 2006 (N=98)	NR				8/106 (7.5%)	NR	AHI: r=0.90
							RDI: r=0.88
							ODI: r=0.92

Source: Table 13, p81 of the ADAR.
Abbreviations: AHI=apnoea hypopnoea index; HSAT/PAT=home sleep apnoea test utilising peripheral arterial tone; NPV=negative predictive value; NR=not reported; ODI=oxygen desaturation index; OSA=obstructive sleep apnoea; PPV=positive predictive value; PSG=polysomnography; RDI=respiratory disturbance index

The ADAR acknowledged (p60) that comparison between the two studies is limited due to the nature of the baseline characteristics, and there are substantial differences in gender, age and BMI. However, the ADAR claimed that HSAT/PAT accuracy to be closely correlated with Level 2 PSG based on the findings of O'Brien et al. (2012) and Zou et al. (2006) (Table 6). The commentary noted the correlation levels differed across the two studies. For AHI, the correlation was considerably lower in the O'Brien et al. (2012) study (r=0.73) compared to the r=0.90 in the Zou et al. (2006) study, with similar inconsistency for RDI (r=0.68 and r-0.88, respectively). The inconsistency in correlation values is a concern, along with the lower correlation observed in the O'Brien et al. (2012) study.

For Zou et al. (2006) sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) values were not available. The commentary considered that given the lack of data, and inconsistent results, there is little support that HSAT/PAT and Level 2 PSG are non-inferior, as claimed by the ADAR. In addition, the patient population was highly selected (pregnant women and patients selected from a hypertension and diabetes database) and is not representative of proposed use of HSAT/PAT on the MBS.

Accuracy of HSAT/PAT versus Level 1 PSG (secondary comparator)
The results from accuracy trials comparing HSAT/PAT with Level 1 PSG are presented in Table 7.

Table 7   Results of accuracy trials comparing HSAT/PAT and Level 1 PSG

Study	HSAT/PAT					Level 1 PSG	Correlation: HSAT/PAT and PSG
	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Failure rate	Failure rate	
Ayas 2003 (N=31)							
AHI 10	82.6%	71.4%					
AHI 15	93.3%	73.3%	0.706	0.923	0%	0%	AHI: r=0.87
AHI 20	90.9%	84.2%		0.957			
AHI 30	83.3%	91.7%	0.714				
Bar 2003 (N=102)	NR				3/31 (9.6%)	2/102 (2.0%)	RDI: r=0.88
Choi 2010 (N=27)							
AHI ≥5	100%	83%	95%	100%	2/27 (7.4%)	NR	AHI: r=0.94 LSAT: r=0.90
AHI ≥15	81%	77%	87%	70%			
AHI ≥30	92%	92%	92%	92%			
Gan 2017 (N=20)							
AHI ≥5	100%	75%					
AHI ≥15	84%	100%	NR	NR	0%	0%	NR
AHI ≥30	80%	100%					
Garg 2014 (N=75)							
AHI ≥5	96%	43%	79%	82%			AHI (home): r=0.73 AHI (lab): r=0.79
AHI ≥10	90%	69%	83%	82%	5%	NR	
AHI ≥15	92%	77%	83%	88%			
Hedner 2004 (N=228)							
RDI <10	90.7%	69.1%					
RDI <20	90.4%	70.5%					
RDI <40	89.1%	68.2%	NR	NR	<4% results unusable	NR	RDI: r=0.87
RDI 40	85.3%	70.8%					
All	88.8%	69.5%					
Ioachimescu 2020 (N=500)							
AHI >5	85.7%	NR	87.3%	NR	NR	NR	AHI: r=0.8
AHI >15	74.5%		98.5%				
Kasai 2020 (N=120)							
AHI ≥30	88.5%	74.6%	NR	NR	1.6%	4.7%	AHI: r=0.896
Körkuyu 2015 (N=30)	NR		96%	NR	NR	NR	AHI: r=0.802
Onder 2012 (N=56)	NR				6.6%	NR	AHI: r=0.94 ODI: r=0.99
Pang 2007 (N=37)							
AHI ≥5	94%	80%					AHI: r=0.929 LSAT: r=0.989
AHI ≥10	96%	79%	NR	NR	NR	NR	
AHI ≥35	83%	72%					
Pillar 2020 (N=84)							
AHI ≥10	83.0%	55.6%	87.3%	47.5%	0%	0%	AHI: r=0.87
AHI ≥15	85.1%	70.3%	78.4%	78.8%			
Pittman 2004 (N=30)							
Home RDI 10	82.%	100%					
Home RDI 15	96%	100%	NR	NR	0%	NR	Home ODI: agreement=0.80
Home RDI 20	80%	89%					
Home RDI 30	92%	82%					
Lab RDI 10	96%	100%					
Lab RDI 15	91%	86%	NR	NR	NR	NR	Home: Lab ODI: agreement=0.83
Lab RDI 20	90%	89%					
Lab RDI 30	92%	82%					
Weimin 2013 (N=28)							
AHI ≥5	95.8%	100%	NR	NR	2/30 (6.7%)	6/34 (17.7%)	AHI: r=0.92
AHI ≥15	93.7%	91.7%					

AHI ≥30	85.7%	100%					
Yuceege 2013 (N=85)	NR						NR
Yalamanchali 2013 (N=909)	NR						AHI+RDI: r=0.889

Source: Table 13, p81 of the ADAR.

Abbreviations: AHI=apnoea hypopnoea index; HSAT/PAT=home sleep apnoea test utilising peripheral arterial tone; LSAT=lowest oxygen saturation; NPV=negative predictive value; NR=not reported; ODI=oxygen desaturation index; OSA=obstructive sleep apnoea; PPV=positive predictive value; PSG=polysomnography; RDI=respiratory disturbance index

The ADAR claimed the included accuracy studies, with the exception of the Ioachimescu et al. (2020)[11], study showed a high correlation between the HSAT/PAT and Level 1 PSG. The ADAR noted the findings of Ioachimescu et al. (2020) differed from all other studies and claimed the results were questionable. The ADAR claimed that in Ioachimescu et al. (2020) the median ODI (3%) was 2.5 while AHI was 18.4 for the Level 1 PSG, suggesting that 85% of the Level 1 PSG arousals were hypopnoeas or apnoeas with no desaturation. The ADAR claimed this to be highly unusual, possibly implausible and inconsistent with previous studies such as Escourrou et al. (2015)[12]. Therefore, the ADAR presented meta-analyses of AHI, sensitivity, specificity, PPV and NPV with and without the Ioachimescu et al (2020), summarised in the Table 8.

The commentary noted that the Ioachimescu et al. (2020) paper criticised HSAT/PAT, stating that the PAT-based testing showed high rates of diagnostic misclassification (30% to 50%) against concomitant gold standard Level 1 PSG, and the diagnostic misclassifications were both over- and under-estimations. The commentary suggested that the ADAR criticism of Ioachimescu et al. (2020) ODI and AHI values may not be entirely reasonable, as the ADAR was comparing mean ODI and AHI from Escourrou et al. (2015) to median values from Ioachimescu et al. (2020). In addition, the population in Escourrou et al. (2015) was patients at lower probability of having OSA, which does not match the population in Ioachimescu et al. (2020), which were patients at high suspicion of OSA.

The pre-MSAC response reiterated that when the median AHI and ODI 3% for Level 1 PSG from Ioachimescu et al. (2020) were compared with Zhang et al. (2020)[13], the wide discrepancy remains (median ODI 3% was 2.5 versus 9.5 respectively, median AHI was 18.4 versus 14 respectively).

[11] Ioachimescu, O. C. et al. (2020) *Journal of Investigative Medicine*. 68(8):1370-1378.
[12] Escourrou, P. et al. (2015) *Journal of Sleep Research*. 24(6):730-738.
[13] Zhang et al. (20250) *Journal of Clinical Sleep Medicine.* 16(4):563-573.

Table 8 Meta-analyses comparing HSAT/PAT with Level 1 PSG

Outcome	Meta-analysis - fixed effects		Meta-analysis - random effects	
	All studies N=16	**Excluding Ioachimescu 2020**	**All studies N=16**	**Excluding Ioachimescu 2020**
AHI correlation (95% CI)	0.862 (0.846, 0.876)	0.895 (0.879, 0.909)	0.887 (0.849, 0.916)	0.864 (0.814, 0.901)
Proportion (95%CI)				
Mild OSA (AHI >5-15)	**Studies N=5**	**Excluding Ioachimescu 2020**	**Studies N=5**	**Excluding Ioachimescu 2020**
Sensitivity	0.959 (0.916, 0.980)	0.959 (0.916, 0.980)	0.959 (0.916, 0.980)	0.959 (0.916, 0.980)
Specificity	0.607 (0.520, 0.687)	0.607 (0.520, 0.687)	0.775 (0.530, 0.914)	0.775 (0.530, 0.914)
	Studies N=4	**Excluding Ioachimescu 2020**	**Studies N=4**	**Excluding Ioachimescu 2020**
PPV	0.623 (0.516, 0.720)	0.623 (0.516, 0.720)	0.694 (0.683, 0.879)	0.697[a] (0.444, 0.868)
NPV	0.790 (0.694, 0.862)	0.790 (0.694, 0.862)	0.799 (0.683– 0.879)	0.799 (0.683, 0.879)
Moderate OSA (AHI>15-30)	**Studies N=9**	**Excluding Ioachimescu 2020**	**Studies N=9**	**Excluding Ioachimescu 2020**
Sensitivity	0.898 (0.875, 0.918)	0.881 (0.838, 0.913)	0.898 (0.875, 0.918)	0.885 (0.837, 0.920)
Specificity	0.662 (0.628, 0.695)	0.766 (0.714 -0.811)	0.776 (0.679, 0.835	0.802 (0.697, 0.877)
	Studies N=5	**Excluding Ioachimescu 2020**	*Studies N=5*	**Excluding Ioachimescu 2020**
PPV	0.743 (0.707, 0.777)	0.669 (0.573, 0.753)	0.711 (0.610, 0.795)	0.693 (0.521, 0.824)
NPV	0.841 (0.780, 0.888)	0.841 (0.780, 0.888)	0.848 (0.770, 0.903)	0.848 (0.770, 0.903)
Severe OSA (AHI>30)	*Studies N=7*	**Excluding Ioachimescu 2020**	*Studies N=7*	**Excluding Ioachimescu 2020**
Sensitivity	0.896 (0.872, 0.917)	0.872 (0.824, 0.909)	0.899 (0.873, 0.921)	0.863 (0.789, 0.913)
Specificity	0.657 (0.620, 0.692)	0.805 (0.744, 0.854)	0.863 (0.734, 0.935)	0.934 (0.772, 0.983)
	Studies N=5	**Excluding Ioachimescu 2020**	*Studies N=5*	**Excluding Ioachimescu 2020**
PPV	0.764 (0.729, 0.797)	0.787 (0.696, 0.856)	0.764 (0.729, 0.797)	0.800 (0.680, 0.883)
NPV	0.657 (0.620, 0.692)	0.805 (0.744, 0.854)	0.863 (0.734, 0.967)	0.895 (0.709, 0.967)

Source: Table8, 26 of the Commentary based on Section B.8, p77-80 of the ADAR with Commentary additions in italics.
Abbreviations: AHI=apnoea hypopnoea index; CI=confidence interval; NPV=negative predictive value; PPV=positive predictive value
a The reported results for studies including and excluding Ioachimescu 2020 should be the same given the ADAR did not use results of Ioachimescu 2020 for the mild OSA subgroup, however the reported results slightly differed due to rounding error in the calculations.

The ADAR claimed that the results of the meta-analyses demonstrated that HSAT/PAT AHI correlated closely with Level 1 PSG. The commentary considered that this claim should be interpreted with caution, as the ADAR did not test for the presence or absence of heterogeneity, as recommended in the Investigative Technical Guidelines. For the analysis of AHI correlation, which used data from 16 studies, there were four correlations included which were not for AHI. In addition, two of the included studies had not been identified by the ADAR as an included study, and one of these two had been identified by the ADAR as being excluded because it had an incorrect population (p135 of the ADAR). Given that a quarter of the included data for the AHI analysis was not AHI data, it is not reasonable to consider the results presented by the ADAR as representative of the correlation of HSAT/PAT and laboratory PSG for AHI.

The commentary also noted that with the exception of sensitivity and specificity for mild OSA, all other analyses for sensitivity and specificity included RDI data. Therefore, the claim made by the ADAR that HSAT/PAT AHI correlated closely with AHI as assessed in laboratory PSG is not strongly supported, as the analyses included RDI data.

The commentary highlighted that a number of simplifications were also made in the meta-analyses for sensitivity, specificity, PPV and NPV against Level 1 PSG which have also reduced precision and reliability of the results including the assumptions that: i) the overall sample size of each study would represent both the total number of patients with disease and without, while this enabled the ADAR to estimate the number of true positive and negative patients in each study in order to calculate a study weight in the meta-analyses, the estimates are imprecise, e.g., the number of true positives with moderate/severe OSA in Ioachimescu (2020) was 264 compared to 455 estimated by the submission and ii) that results reported for the combined moderate/severe OSA from Ioachimescu 2020 also applies to the contributing subgroups. Sensitivity/specificity/PPV/NPV for the individual component subgroups (calculated using results reported in Figure 1 of the publication) suggest vastly different results compared to the combined moderate/severe OSA group (e.g., sensitivity/specificity for moderate and severe OSA was 41%/75%[14] and 83%/79%[15] respectively versus 91%/61% for the combined moderate/severe OSA group). Furthermore, there was also an error in the analysis of NPV, as the ADAR included incorrect patient numbers.

Overall, given the inclusion of an excluded study along with another previously unidentified study, the use of RDI data for the AHI correlation analyses, along with what appears to be an error for the analysis of NPV for moderate OSA and some simplifications in the analyses to assist calculations which may reduce precision and reliability of the results, the results of the meta-analyses presented by the ADAR may not accurately represent the accuracy of HSAT/PAT.

The commentary also noted that the ADAR did not provide any evidence or discussion linking the results observed for the Level 2 PSG studies to the reference standard of Level 1 PSG. As noted above, there were also considerable concerns around the comparative HSAT/PAT vs. Level 1 PSG evidence presented (e.g. RDI evidence included in analyses of AHI) that limit the strength of the evidence. Also, all of the comparative HSAT/PAT vs. Level 1 PSG studies were based on the use of HSAT/PAT in a sleep laboratory setting, which does not correspond to the proposed use of HSAT/PAT, which is in a home-based setting. It is uncertain whether the results observed for HSAT/PAT in clinical practice (i.e. laboratory setting) will be observed in a home-based setting.

The pre-MSAC response claimed that the importance of specificity, sensitivity and negative and positive predictor values had been over-emphasised. The pre-MSAC response claimed AHI correlation is of far more clinical importance, as AHI is a continuous measure and the primary value considered in diagnosis of OSA. The pre-MSAC response reiterated claims that the studies included in the ADAR (which did not include Zhang et al. 2020) were conducted prior to the introduction of manual editing so will not represent the current accuracy. The pre-MSAC response reiterated that the ratified PICO did not specify comparing Level 1 to Level 2 PSG. The pre-MSAC response reiterated claims that the

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[14] Calculated from a 2x2 table calculated from results reported in Figure 1 of the publication, composed of true positive (TP)=56, false positive (FP)=90, false negative (FN)=79, true negative (TN)=275. Sensitivity=56/(56+79)=41%, specificity=275/(275+90)=75%

[15] Calculated from a 2x2 table calculated from results reported in Figure 1 of the publication composed of TP=128, FP=27, FN=72, FP=273. Therefore sensitivity =128/(128+27)=83%, specificity=273/(273+72)=79%

performance of HSAT/PAT would not be enhanced when used in the laboratory compared to home, claiming the attendance of a technician during a HSAT/PAT study will not enhance the performance of HSAT/PAT as there are no tasks or adjustments for the technician to perform.

Clinical claim
Based on the evidence presented, the ADAR concluded that HSAT/PAT is non-inferior to the main comparator Level 2 PSGs and HSAT/PAT is non-inferior to the secondary comparator Level 1 PSG.

However, the commentary considered that given the points raised above regarding the evidence presented, particularly the limited applicability of the HSAT/PAT vs Level 2 PSG studies to the proposed patient population, the varying correlation levels in the HSAT/PAT vs Level 2 PSG studies, the lack of consideration of the level of heterogeneity in the meta-analyses of HSAT/PAT vs Level 1 PSG studies presented, along with inclusion of RDI data in the meta-analyses of AHI (a quarter of the included data for the AHI analysis was not AHI data; 4 of 16 studies), and the fact that all study data comparing HSAT/PAT with Level 1 PSG was based on sleep laboratory use of HSAT/PAT instead of use in the home, there is limited support for the ADAR's claim of non-inferiority.

Translation Issues
The ADAR stated (p91) that no translation issues were identified. However, the commentary noted that the two studies comparing HSAT/PAT with Level 2 PSG (O'Brien et al. 2012; Zou et al. 2006) have limited applicability and represent only a small subgroup of the patient population in the proposed MBS item descriptor, and the majority of the studies comparing HSAT/PAT with Level 1 PSG were for patients at risk of suspected OSA, which does not directly correspond to the requested listing for patients at high risk of moderate to severe OSA.

12. Economic evaluation

On the basis of the claim of non-inferiority, the ADAR presented a cost-minimisation analysis. A summary of the key characteristics of the economic evaluation is given in the table below.

Table 9   Summary of the economic evaluation – cost-minimisation

Perspective	Australian healthcare system
Comparator	Main comparator: Level 2 PSG (at home) Secondary comparator: Level 1 PSG
Type of economic evaluation	Cost-minimisation
Sources of evidence	Systematic review
Time horizon	5 years
Software packages used	Excel 2012

Source: Table 16, p93 of the ADAR.
Abbreviations: PSG=polysomnography

The cost-minimisation analysis presented by the ADAR included current usage of Level 1 and Level 2 PSGs on the MBS, estimated usage of those MBS items, the number of eligible patients, the expected substitution of Level 1 and Level 2 PSG by HSAT/PAT, and estimated usage of HSAT/PAT. These estimates were presented over 5 years, which resembled financial estimates (Section E of the Investigative Technical Guidelines).

The key assumptions of the cost-minimisation as identified by the ADAR are as follows:

- There will be no increase in the number of sleep studies with the introduction of HSAT/PAT.
- There will be no difference in treatment of OSA due to any differences in the classification of OSA, and it is unlikely there will be a change in the OSA treatment pathway as a result of using HSAT/PAT.
- 5% of patients who receive a Level 2 PSG (at home) will not have a satisfactory result and will receive an additional Level 1 PSG. The same is assumed for use of HSAT/PAT. The commentary noted that this may not be reasonable as the failure rate for HSAT/PAT in the two HSAT/PAT vs Level 2 PSG studies was 5.4% and 7.5%, and in the HSAT/PAT vs Level 1 PSG studies ranged from 0% to 9.6%.
- Up to 10% of patients who currently receive a Level 1 PSG may be eligible for HST/PAT instead (advice of local sleep specialists).
- Based on use of HSAT/PAT in markets where it has been launched, it is assumed 80% of patients will use the single use device and 20% will use the re-usable HSAT/PAT.
- All Level 1 PSGs were performed in-hospital, either a public/private hospital, and the costs assigned for Level 1 PSG included DRG costs and 75% MBS rebate.

The ADAR estimated that 95% of patients who currently receive a Level 2 PSG (at home) would be eligible to receive HSAT/PAT instead (on the basis that 5% of patients would not be eligible due to one of the contraindications for HSAT/PAT) and 10% of patients who currently receive Level 1 PSG would be eligible to receive HSAT/PAT instead. The ADAR assumed 10% of Level 2 PSGs will be substituted by HSAT/PAT, increasing to 30% in 2025 (Year 5). The commentary noted that the proposed uptake of 10% in Year 1, increasing to 15% in Year 2, 20% in Year 3, 25% in Year 4 and 30% in Year 5 may be an underestimate of usage given the ADAR has advocated that HSAT/PAT will offer simpler use than Level 2 PSG.

The comparative costs for Level 1 and Level 2 PSG and HSAT/PAT as presented by the ADAR are shown in Table 10.

Table 10 Comparative cost for Level 2 and Level 1 PSG with and without substitution of HSAT/PAT

	Year 1	Year 2	Year 3	Year 4	Year 5
Cost of Level 1 and Level 2 PSG					
Cost: Level 2 PSG	$59,695,382	$62,253,930	$64,995,143	$67,613,607	$70,214,971
Cost: Level 1 PSG	$84,402,110	$88,022,960	$91,904,773	$95,608,535	$99,289,464
Cost: Level 1 and Level 2 PSG – total cost	$144,097,492	$150,276,890	$156,899,916	$163,222,142	$169,504,435
Cost of Level 1 and Level 2 PSG if HSAT/PAT is MBS listed					
Cost: Level 2 PSG	$54,024,321	$53,382,745	$52,646,066	$51,555,375	$50,203,704
Cost: Level 1 PSG	$83,558,089	$86,702,616	$90,066,677	$93,218,322	$96,310,780
Cost: Level 1 and Level 2 PSG – total cost	$137,582,409	$140,085,361	$142,712,743	$144,773,697	$146,514,484
Cost of HSAT/PAT					
HSAT/PAT cost – substituting for Level 2 PSG	$5,622,218	$8,794,780	$12,242,718	$15,919,926	$19,838,915
HSAT/PAT cost – substituting for Level 1 PSG	$254,690	$398,425	$554,660	$721,266	$898,842
HSAT/PAT total cost	$5,876,908	$9,193,205	$12,797,378	$16,641,193	$20,737,757
Cost: Level 1 PSG, Level 2 PSG + HSAT/PAT	$143,459,318	$149,278,565	$155,510,121	$161,414,889	$167,252,241
Difference with Level 1 and Level 2 PSG	-$638,174	-$998,325	-$1,389,794	-$1,807,252	-$2,252,193

Source: Table 25, p109 of the ADAR.
Abbreviations: HSAT=home sleep apnoea test; PAT=peripheral arterial tone; PSG=polysomnography

The ADAR noted that the costs include follow-up Level 1 PSGs for patients whose Level 2 PSG or HSAT/PAT did not report a satisfactory result, or required a repeat test for another reason.

The ADAR applied a time horizon of 5 years to its cost-minimisation analysis, with costs determined on a yearly basis. The cost per patient is the sum of the MBS item fees for proposed for HSAT/PAT test plus physician consult fees (Table 11).

Table 11 Estimated cost of HSAT/PAT per patient

HSAT/PAT	Cost: test	Number:	physician consults	Cost[a]: physician consults	Total cost
Single use 80% of patients	$293.90 (85% benefit)	Mild OSA:	MBS 104: 1 MBS 105: 3	$190.90	$484.80
		Moderate OSA:	MBS 104: 1 MBS 105: 3.65	$215.76	$509.66
		Severe OSA:	MBS 104: 1 MBS 105: 5	$267.40	$561.30
Re-usable 20% of patients	$268.40 (85% benefit)	Mild OSA:	MBS 104: 1 MBS 105: 3	$190.90	$459.30
		Moderate OSA:	MBS 104: 1 MBS 105: 3.65	$215.76	$484.16
		Severe OSA:	MBS 104: 1 MBS 105: 5	$267.40	$535.80

Source: Table 11, p30 of the Commentary
Abbreviations: HSAT=home sleep apnoea test; OSA=obstructive sleep apnoea; PAT=peripheral arterial tone
[a] MBS item costs at 85% benefit. MBS item 104 $76.15; MBS item 105: $38.25

ESC noted MBS items 110/116 ($157.95/$79.05) and 132/133 ($276.25/$138.30) should have been used instead of MBS items 104/105.

The ADAR presented sensitivity analyses for the cost-minimisation analysis, varying the following components of the analysis:

- Proportion eligible: The proportion of patients currently receiving Level 2 PSG who will be eligible for HSAT/PAT (base case: 95%) was increased by 5% and decreased by 15%. The proportion of patients currently receiving Level 1 PSG was increased by 10% and decreased by 10% (base case 10%)
- Substitution of Level 1 and Level 2 PSG by HSAT/PAT: The usage of HSAT/PAT was increased by 10% and by 5% (base case: 10% in Year 1, increasing by 5% per year)
- Single use and repeatable use HSAT/PAT: The proportion of patients using single use HSAT/PAT and re-usable HSAT/PAT was changed to 70:30 and to 90:10 (base case: 80:20).
- Proportion having follow-up Level 1 PSG: Altered to 7% and to 3% (base case: 5%).

The results of the sensitivity analyses (including additional conducted for the commentary) are provided in Table 12.

Table 12 Sensitivity analysis for the cost-minimisation analysis

	Year 1	Year 2	Year 3	Year 4	Year 5
Base case	**-$638,174**	**-$998,325**	**-$1,389,794**	**-$1,807,252**	**-$2,252,193**
Proportion eligible for Level 2 PSG (base case: 95%)					
100% eligible	-$640,745	-$1,002,346	-$1,395,392	-$1,814,531	-$2,261,265
80% eligible	-$630,462	-$986,261	-$1,373,001	-$1,785,415	-$2,224,980
Proportion eligible for Level 1 PSG (base case: 10%)					
20% eligible	-$1,227,505	-$1,920,245	-$2,673,230	-$3,476,199	-$4,332,035
0% eligible	-$48,843	-$76,405	-$106,359	-$138,305	-$172,352
Substitution of Level 2 PSG (base case 10% in Year 1 increasing by 5% per year to 30% in Year 5)					
20% in Year 1 for Level 2 PSG	-$687,017	-$1,049,262	-$1,442,974	-$1,862,574	-$2,309,644
5% in Year 1 for Level 2 PSG	-$613,753	-$972,856	-$1,363,205	-$1,779,591	-$2,223,468
50% in Year 1 for Level 2 PSG	*-$833,547*	*-$1,202,072*	*-$1,602,513*	*-$2,028,541*	*-$2,481,996*
Substitution of Level 1 PSG (base case 10% in Year 1 increasing by 5% per year to 30% in Year 5)					
20% in Year 1 for Level 1 PSG	-$1,227,505	-$1,612,938	-$2,031,512	-$2,474,831	-$2,945,474
5% in Year 1 for Level 1 PSG	-$343,509	-$691,018	-$1,068,936	-$1,473,463	-$1,905,553
Single use: re-usable HSAT/PAT (base case: 80:20)					
70:30	-$663,702	-$1,038,258	-$1,445,383	-$1,879,538	-$2,342,274
90:10	-$612,646	-$958,392	-$1,334,205	-$1,734,967	-$2,162,113
Follow-up Level 1 PSG for HSAT/PAT (base case: 5%)					
3%	-$1,025,562	-$1,604,312	-$2,233,358	-$2,904,188	-$3,619,162
7%	-$250,787	-$392,337	-$546,231	-$710,316	-$885,225
10%	*$330,295*	*$516,644*	*$719,115*	*$935,088*	*$1,165,229*
Level 1 PSG 75% rebate					
50%[a] of Level 1 PSG at 75% rebate and 50% at 85% rebate	*$966,675*	*$668,182*	*$342,693*	*-$12,751*	*-$396,712*

Source: Table 38, p 94 of the Commentary, compiled based on Table 26, p110-11 of the ADAR with Commentary in italics
Abbreviation: HSAT=home sleep apnoea test; PAT=peripheral arterial tone; PSG=polysomnography
[a] 50% refers to the number of Level 1 PSGs.

The sensitivity analyses indicated that MBS listing of HSAT/PAT would remain cost saving when the proportion eligible, the substitution of PSG, the proportion of single use and re-usable HSAT/PAT, and proportion receiving a follow-up Level 1 PSG were altered. The commentary noted that the sensitivity analyses show a large component of the estimated saving is due to the inclusion of follow-up Level 1 PSG when results are inconclusive, at a rate of 5%. When the failure rate of HSAT/PAT is increased to 10% from the 5% used in the base case, the estimated saving becomes a cost of $330,295 in Year 1 increasing to $1.2M in Year 5. The ADAR has not provided strong support for the claimed 5% retest level, and the failure rate for HSAT/PAT in the selected Level 2 studies was 5.4% and 7.5%, in both cases greater than 5%, and another study cited by the ADAR (Phua 2020) had a failure rate of 10.5% for HSAT/PAT.

The ADAR assumed 100% of Level 1 PSG are conducted in-hospital, assigned costs for Level 1 PSG that included DRG costs and applied the 75% MBS rebate for Level 1 PSG. However, the Department advised that MBS claiming data for MBS item 12203 (Level 1 sleep studies) indicated that approximately 50% of Level 1 PSG are claimed in-hospital (75% rebate) and 50% are claimed out-of-hospital (85% rebate). Therefore, the commentary also presented a sensitivity analysis in which the 75% rebate for Level 1 PSG was applied for half

of the patients and the 85% rebate for Level 1 PSG applied for the other half of patients. This resulted in a net cost of $966,675 in Year 1, and a net saving in Year 5 of -$396,712, for an overall net cost over the first 5 years of listing of $1.6M.

The pre-ESC response clarified that any Level 1 PSGs performed in non-hospital clinics are only eligible for an 85% MBS rebate and are not covered by PHI, so cannot claim a hospital admission, and therefore the apportioned DRG. The sensitivity analysis by the commentary, where 50% of Level 1 PSG are performed out-of-hospital did not adjust the hospital costs. The pre-ESC response presented a corrected calculation that resulted in a net saving of -$391,949 in Year 1 increasing to a net saving in Year 5 of -$1,383,226.

13. Financial/budgetary impacts

The financial implications for the proposed listing of HSAT using PAT are summarised in Table 13.

Table 13 Estimated usage and cost to the MBS for the listing of HSAT/PAT

	Year 1	Year 2	Year 3	Year 4	Year 5
Use and cost of Level 1 and Level 2 PSG on the MBS if HSAT/PAT is listed					
Number of Level 1 PSG	42,951	44,568	46,297	47,917	49,506
Cost: Level 1 PSG	$28,189,097	$29,249,933	$30,384,830	$31,448,067	$32,491,336
Number of Level 2 PSG	91,235	90,151	88,907	87,065	84,783
Cost: Level 2 PSG	$45,198,207	$44,661,448	$44,045,122	$43,132,621	$42,001,776
Cost: Level 1 and Level 2 PSG	$73,387,305	$73,911,381	$74,429,952	$74,580,687	$74,493,113
Use and cost of HSAT/PAT					
Number eligible for Level 1 PSG	*4,339*	*4,525*	*4,724*	*4,915*	*5,104*
Number eligible for Level 2 PSG	*95,771*	*99,876*	*104,274*	*108,475*	*112,648*
Proportion Level 1 patients using HSAT/PAT	*10%*	*15%*	*20%*	*25%*	*30%*
Proportion Level 2 patients using HSAT/PAT	*10%*	*15%*	*20%*	*25%*	*30%*
Number of services: Level 1 HSAT/PAT	*434*	*679*	*945*	*1229*	*1531*
Number of services: Level 2 HSAT/PAT	*9,577*	*14,981*	*20,855*	*27,119*	*33,794*
Number of services: Total HSAT/PAT	10,011	15,660	21,800	28,347	35,326
Cost: HSAT/PAT	$4,908,439	$7,678,235	$10,688,469	$13,898,853	$17,320,335
Cost: Level 1 and Level 2 plus HSAT/PAT	$78,295,744	$81,589,616	$85,118,422	$88,479,540	$91,813,448
Cost: Level 1 and Level 2 without HSAT/PAT	$78,416,606	$81,778,684	$85,381,623	$88,821,799	$92,239,966
Net MBS cost	**-$120,862**	**-$189,068**	**-$263,201**	**-$342,259**	**-$426,518**

Source: Table 12, p31 of the Commentary, compiled based on Table 24, p108 and Table 27, p112 of the ADAR with Commentary additions in italics
Abbreviations: HSAT=home sleep apnoea test; MBS=Medicare Benefits Schedule; PAT=peripheral arterial tone; PSG=polysomnography

The commentary noted that approximately half of the estimated cost saving is due to the lower requested price for the re-usable device ($30.00 less), which is used by 20% of patients, with the remainder due to use of HSAT/PAT instead of Level 1 PSG.

The estimated impact to the MBS did not include the costs for the cost of a follow-up Level 1 PSG for patients whose HSAT/PAT or Level 2 PSG did not report satisfactory results, or required a repeat test for another reason. However, the commentary noted that inclusion of the cost of follow-up Level 1 tests is more likely to accurately reflect the estimated cost to the

MBS. The pre-ESC response presented updated MBS costs that included repeat Level 1 PSG (Table 14).

The ADAR did not provide any discussion of possible sources of uncertainty in the financial estimates, nor were any sensitivity analyses provided.

Table 14 Pre-ESC response -updated MBS Costs

Current MBS	2021	2022	2023	2024	2025
Level 2 PSG utilisation and cost	100,812	105,133	109,762	114,184	118,577
	$54,512,191	$56,848,587	$59,351,788	$61,742,898	$64,118,392
Level 1 PSG utilisation and cost	43,385	45,246	47,242	49,145	51,038
	$29,923,979	$31,207,718	$32,583,979	$33,897,113	$35,202,152
Total	$84,436,171	$88,056,305	$91,935,767	$95,640,011	$99,320,544
MBS with HSAT/PAT	**2021**	**2022**	**2023**	**2024**	**2025**
Level 2 HSAT utilisation and cost	91,235	90,151	88,907	87,065	84,783
	$49,333,533	$48,747,664	$48,074,949	$47,078,959	$45,844,651
Level 1 PSG utilisation and cost	42,951	44,568	46,297	47,917	49,506
	$29,624,740	$30,739,602	$31,932,299	$33,049,685	$34,146,087
HSAT/PAT	10,011	15,660	21,800	28,347	35,326
	$5,362,199	$8,388,049	$11,676,563	$15,183,730	$18,921,510
Total	$84,320,472	$87,875,315	$91,683,810	$95,312,374	$98,912,248
Differential	**-$115,699**	**-$180,991**	**-$251,957**	**-$327,636**	**-$408,296**

Source: Table 3, p5 of the pre-ESC response
Abbreviations: HSAT=home sleep apnoea test; MBS=Medicare Benefits Schedule; PAT=peripheral arterial tone; PSG=polysomnography

14.   Key Issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
Comparative safety	No safety issues identified by the ADAR however, the studies reviewed did not directly assess safety. Potential harms may include over and under-diagnosis.
Comparative effectiveness	The is no evidence for direct effectiveness of HSAT/PAT in terms of health outcomes.
	The ADAR only considered the effectiveness of HSAT/PAT in terms of the comparative diagnostic performance (i.e. test accuracy) of HSAT/PAT versus the comparators.
	Limited evidence (k=2) with limited applicability on the comparative accuracy of HSAT/PAT versus Level 2 PSG (main comparator).
	There is a larger evidence base (k=16) comparing HSAT/PAT accuracy with Level 1 PSG (secondary comparator), but the setting is laboratory-based which is not representative of the intended setting of use for HSAT/PAT. Although results report correlation (r >0.7), there is one contrasting study, raising uncertainty as to whether level of correlation would occur in real world experience and lead to discrepant results for some patients, and what that impact would be.

Access and equity	The single use HSAT/PAT requires a smartphone and internet access; it may improve access in regional and remote communities. However, no evidence was presented that improved access would lead to changed clinical management or improved health outcomes.
HSAT/PAT technology and market	HSAT/PAT devices, including the WatchPAT HSAT/PAT device described in this application are currently available as a Direct to Consumer products.
	Competitor HSAT devices are available in Australia which are similar to the WatchPAT HSAT/PAT in that they measure a PPG signal but differ in the other parameters measured, and may provide multi-night analysis.
MBS item descriptor, fee and co-claiming	MSAC may want to consider:
	• A new descriptor for the service aligned to MBS item 12250, fit for purpose for PAT-based HSAT, noting likely other similar technologies to future proof (i.e. device agnostic).
	• Department advice that the MBS fee should cover the professional service only and the implications whether the MBS item fee does or does not include costs for the disposable/reusable device (i.e. policy implications, out-of-pocket costs to patients for the device).
	• Only one MBS item covering the professional services for HSAT/PAT would be required if the cost of the device/consumables is separated out.
	• Reducing the proposed fee which ESC considers to be high as it includes the cost of HSAT/PAT device and as HSAT/PAT is not equivalent to Level 2 PSG. The wording of the descriptor needs consideration in relation to exchangeability of those PAT devices that have not been assessed in this application.
	• Include similar restrictions as those for MBS item 12250, such as other sleep items, once per year, age over 18.
Uptake of HSAT/PAT	The uptake of HSAT/PAT is highly uncertain. HSAT/PAT is unlikely to directly substitute Level 2 and Level 1 PSGs. There is likely potential for HSAT/PAT to increase the overall market as the device is easier to apply than the comparators and may increase access in rural/regional communities.
Substitution of Level 1 PSG	The HSAT/PAT is unlikely to substitute for a Level 1 PSG to the degree specified, as the ADAR did not adequately justify which (and how many) patients who would otherwise require a Level 1 PSG could swap to a HSAT/PAT. Further, Level 1 PSG usage have been decreasing over time.
Economic evaluation	The economic evaluation presented was not a cost-minimisation analysis, but a financial estimate over 5 years which is highly uncertain and not informative.
Financial implications	The estimated impact of listing HSAT/PAT to the MBS is highly uncertain. The estimated savings to the MBS are due to the lower requested MBS fee for the re-usable HSAT/PAT MBS item and substitution of Level 1 PSG which have not been adequately justified and are highly uncertain.

ESC Discussion

ESC noted that this application was for Medicare Benefits Schedule (MBS) listing of home sleep apnoea test (HSAT) utilising peripheral arterial tone (PAT) for the diagnosis of obstructive sleep apnoea (OSA).

ESC noted that HSAT/PAT uses a patient worn device, such as the WatchPAT which measures PAT signal, heart rate, oximetry, actigraphy (body movement), body position, snoring sound level, and chest motion via three points of contact. ESC noted that the parameters measured by HSAT/PAT devices such as the WatchPAT are not equivalent to the parameters measured during polysomnography (PSG) sleep studies which, for Level 2 PSG includes airflow, continuous electromyography (EMG), continuous electrocardiogram (ECG), continuous electroencephalogram (EEG), electro-oculography (EOG), oxygen saturation and respiratory effort. ESC noted that, in addition to the WatchPAT device nominated in this application, another HSAT device, the NightOwl HSAT (ARTG 319834 & 320061) is also available in Australia. ESC also noted that:

- accreditation by the Australasian Sleep Association (ASA) and the National, Association of Testing Authorities (NATA) should be required,
- specific training in understanding of the PAT signal should be mandatory,
- either a sleep technologist or a sleep physician may score the test and a sleep physician should determine if further treatment is needed,
- guidelines for manual review and adjustment of automated scoring are available, and
- manual review is based on review of the automated report and takes 10-15 minutes.

ESC noted that the consultation feedback received mixed support. Some feedback advised that the WatchPAT HSAT/PAT device was more appropriately classified as a Level 3 sleep study, and is not equivalent to a Level 2 sleep study (unattended polysomnography [PSG]) as claimed in the Applicant Developed Assessment Report (ADAR) as the HSAT/PAT devices do not continuously and directly measure the same parameters as a Level 2 PSG and does not specifically measure respiration. ESC agreed with consultation feedback that there is a risk of over diagnosis of OSA using HSAT/PAT devices or other sleep study devices, that treatment benefits do not correlate well with sleep study results, and there are commercial implications which ESC considered are likely to increase the market. ESC noted feedback that the proposed MBS fee for HSAT/PAT is not reflective of the different effort, cost, specialization, and application involved with a Level 2 PSG sleep study. ESC also noted consumer feedback queried whether the single use disposable device is recyclable.

ESC also noted that the HSAT/PAT devices require smart phone and internet access, which raises equity issues for people who do not have this access. However, ESC noted that the devices can be posted to a patient's home with access to 24-hour support, and agreed with consultation feedback that these devices may increase equity for rural and regional patients.

ESC noted that the ADAR proposed two new MBS items for HSAT/PAT: one for conducting HSAT/PAT using a single use HSAT/PAT device and one for conducting HSAT/PAT using a cheaper reusable HSAT/PAT device. ESC noted that the proposed MBS items were the same except for the proposed fee and that the proposed fees include both professional service costs and consumable device costs. However, the ADAR did not provide a breakdown of the cost of the device, consumables and service. ESC noted advice from the Department that MBS item numbers are intended to take into consideration only the professional service and not the cost of devices or consumables. ESC noted the applicant stated the cost for the single use WatchPAT is **redacted** and disposables for the reusable WatchPAT cost **redacted**.

However, ESC noted that the WatchPAT®ONE is available online for $229.95 and that a competitor device is available to purchase online for $149.00, which includes multi-night (3 night) assessment, consultation and an analysis report. ESC considered that only one new MBS item for HSAT/PAT should be proposed with a single proposed fee commensurate with the professional services required however, it was unclear to ESC how much of the Applicant proposed MBS fees for HSAT/PAT are attributable to the professional service.

ESC noted the test requirements listed in the proposed MBS descriptor could potentially make the proposed MBS item device gnostic (e.g. overnight, the number and type of parameters measured). ESC considered that the item descriptor criteria should be reviewed and revised to ensure the proposed MBS item is device agnostic, while not permitting use of devices that have not been assessed for comparable clinical or cost-effectiveness. ESC also considered that the applicant should clarify why the proposed MBS descriptor for HSAT/PAT specifies 'scoring in epochs of not more than 20 minutes' and why this is different to the MBS item for Level 2 PSG which specifies 'scoring in epochs of not more than 1 minute'. ESC also considered that the item descriptor should apply the same claiming restrictions as MBS item 12250 (e.g. a frequency restriction to limit billing to once per patient in a 12 month period.) and is a Type C: out-of-hospital procedure.

ESC noted the primary comparator is Level 2 PSG and the secondary comparator is Level 1 PSG. ESC noted the ADAR clinical management algorithm depicted HSAT/PAT substituting both Level 2 PSG and Level 1 PSG. However, ESC considered that the ADAR did not provide sufficient information to justify the use of HSAT/PAT in patients who otherwise would require an attended Level 1 PSG (i.e. patients who are unsuitable for an unattended PSG [Level 2] and require an attended PSG [Level 1]), noting that the ADAR did not demonstrate how patients who have difficulty communicating, a language barrier, mobility problems or other physical disabilities may be suitable for HSAT/PAT in place of Level 1 PSG.

ESC noted the clinical evidence base consisted of two cohort studies comparing the accuracy of HSAT/PAT with Level 2 PSG (main comparator), and 16 studies comparing the accuracy of HSAT/PAT with Level 1 PSG (secondary comparator). ESC noted that the ADAR did not provide any evidence linking Level 2 and Level 1 PSG. ESC noted the patient population in the two studies comparing HSAT/PAT with Level 2 PSG were highly selected (pregnant women and patients selected from a hypertension and diabetes database) and as such were not considered representative of the population in the proposed MBS item HSAT/PAT. ESC also noted the 16 studies comparing HSAT/PAT with Level 1 PSG were conducted in a sleep laboratory and that the results in this setting may not be representative of results achieved in a home-based setting.

Regarding comparative safety, ESC noted the included studies comparing HSAT/PAT with Level 2 and Level 1 PSG generally did not directly assess safety outcomes. ESC also noted the studies did not consider or evaluate potential for harm through misdiagnosis, overtreatment or psychosocial harms (e.g. anxiety, labelling).

Regarding comparative effectiveness, ESC noted that the ADAR did not consider the direct effectiveness of HSAT/PAT in terms of health outcomes, and only presented evidence on the comparative diagnostic performance (i.e. test accuracy) of HSAT/PAT versus the comparators. In considering the comparative accuracy of HSAT/PAT versus Level 2 PSG, ESC noted that the results suggest good correlation of HSAT/PAT with Level 2 PSG but was concerned with the inconsistencies in correlation values reported across the studies. ESC

noted the correlation of HSAT/PAT AHI with Level 2 PSG AHI was considerably lower in the O'Brien et al. (2012) study (r = 0.73) compared to the Zou et al. (2006) study (r = 0.90). Similarly, for the Respiratory Disturbance Index (RDI), the correlation between HSAT/PAT and Level 2 PSG was inconsistent across the two studies (O'Brien et al. 2012, r = 0.68; Zou et al. 2006, r = 0.88). ESC expressed concern with the inconsistency in correlation values and lower correlation observed in the O'Brien et al. (2012) study. ESC also noted that HSAT/PAT sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were not available from the Zou et al. (2006) study.

In considering the comparative accuracy of HSAT/PAT versus Level 1 PSG, ESC noted the meta-analyses using data from the 16 accuracy trials comparing HSAT/PAT with Level 1 PSG. ESC noted the findings in Ioachimescu (2020)[16] differed from all other studies, that these study authors stated that PAT-based testing showed high rates of diagnostic misclassification (30% to 50%) against concomitant gold standard PSG, and the diagnostic misclassifications were both over- and under-estimations. In regards to AHI correlation, ESC noted that while the results suggest good correlation of HSAT/PAT with Level 1 PSG, ESC also noted that the sensitivity of HSAT/PAT declines with OSA severity. ESC also agreed with the commentary that the meta-analysis claims for HSAT/PAT should be interpreted with caution due to the issues with the meta-analyses identified by the commentary, such as inclusion of RDI correlation data in the analysis of AHI correlation, and simplifications and assumptions in the analyses to assist calculations which may reduce precision and reliability of the results.

Overall, ESC agreed with the commentary that clinical claim that HSAT/PAT is non-inferior, in regard to safety and efficacy, to main comparator Level 2 HSAT and secondary comparator Level 1 PSG, is not strongly supported by the evidence presented in the ADAR.

ESC noted that the ADAR did not present a cost-minimisation analysis as claimed, instead the economic analysis was essentially a financial estimate over 5 years for the overall health system with each year presented separately. ESC noted several issues with the economic evaluation:

- The ADAR assumed HSAT/PAT would not increase sleep apnoea tests numbers. However, ESC considered this assumption to be highly uncertain and considers there is likely potential that listing HSAT/PAT would grow the market as it is easier to administer and simpler to use at home.

- The ADAR assumed 5% of patients receiving HSAT/PAT or Level 2 PSG will have no result and require a follow up Level 1 PSG. However, ESC noted that the failure rate for HSAT/PAT in studies ranges from 0% to 9.6%.

- The ADAR assumed up to 10% of patients who receive a level 1 PSG can swap to HSAT/PAT. ESC considered this assumption was uncertain as it was unclear which patients who aren't suitable for an unattended Level 2 PSG and require attend Level 1 PSG can then swap to a HSAT/PAT.

- The ADAR assumed all Level 1 PSG are conducted in a hospital and therefore applied hospital costs to all patients receiving Level 1 PSG. ESC noted that in practice, the MBS claiming data shows in practice 50% are conducted in-hospital and 50% conducted out-of-hospital in private clinics but that it may be reasonable to assume similar costs.

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[16] Ioachimescu O, et al. (2020) *Journal of Investigative Medicine*. 68(8):1370-1378.

- The ADAR did not identify any applicability issues. However, ESC agreed with the commentary that there are applicability issues given that the studies comparing HSAT/PAT with Level 2 PSG have limited applicability and represent only a subgroup of the proposed population (e.g. pregnant women, patients selected from a hypertension and diabetes database).

- The economic analysis assumed 80% of patients would use the single-use device and 20% the reusable device. However, ESC noted that this assumption was not justified.

ESC noted the cost per patient used in the ADAR economic analysis was based upon the cost of the test and physician consults using MBS items 104/105 ($89.55/$45). ESC considered the cost per patient was underestimated as the analysis should have used MBS items 110/116 ($157.95/$79.05) and 132/133 ($276.25/$138.30).

ESC noted the results of the economic analysis indicated a cost saving of -$638,174 in year 1 rising to -$2,252,193 as uptake increase over time. ESC noted the cost savings are largely driven by reduced hospital costs through substitution of Level 1 PSG with HSAT/PAT, but ESC considered that substitution of Level 1 PSG with HSAT/PAT was highly uncertain as the ADAR had not adequately justified which (and how many) patients who otherwise required Level 1 PSG could swap to a HSAT/PAT. ESC noted that the economic analysis did not take into consideration sensitivity and specificity of HSAT/PAT. ESC noted concerns with high sensitivity and poor specificity, a consequence of which is false positives leading to subsequent investment in treatment. Overall, ESC considered the economic analysis to be highly uncertain and not informative.

ESC noted the financial estimates presented in the ADAR appear to be market-share approach with direct substitution of Level 1 and Level 2 PSG which, was essentially the same as the economic analysis but with hospital costs removed to provide an estimate of the financial impact to the MBS. ESC also noted the financial analysis did not include eligibility, rate of uptake or determination of costs. ESC considered the estimated number of Level 1 PSG to be highly uncertain and likely over-estimated as the ADAR estimated a linear increase in the use of Level 1 PSG when 2017–2019 data showed a year-on-year decrease in use estimated, and the estimated number inappropriately took into consideration use of MBS items 12204 and 12205 which are note for primary diagnosis of OSA using Level 1 PSG. ESC noted the estimated savings to the MBS are due to the lower requested MBS fee for the re-usable HSAT/PAT MBS item and substitution of level 1 PSG. ESC considered that including this device on the MBS would likely expand testing, which could result in overdiagnosis of OSA and increased sales of associated devices to treat OSA. ESC considered it unlikely that listing HSAT/PAT on the MBS would lead to changed clinical management or improved health outcomes, and no evidence was presented to suggest that it would. Overall, ESC considered the financial estimates presented in the ADAR to be highly uncertain.

15.   Other significant factors

Nil

16. Applicant comments on MSAC's Public Summary Document

The applicant would like to thank MSAC for their consideration of this application and the work undertaken throughout the application process. While we are disappointed in the outcome, we will consider MSACs advice in any future submission.

17. Further information on MSAC

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