Medical Services Advisory Committee

Public Summary Document

Application No. 1130 – Unattended Sleep Studies in the Diagnosis and Reassessment of Obstructive Sleep Apnoea

Applicants: **Australasian Sleep Association / Thoracic Society of Australia and New Zealand**

Healthy Workplace Solutions Pty Ltd, trading as Healthy Sleep Solutions

Date of MSAC consideration: **48th MSAC meeting, 29-30 March 2010**

1. Purpose of Application

In May 2008 an application for public funding of all unattended Obstructive Sleep Apnoea (OSA) studies was received from the Australasian Sleep Association/Thoracic Society of Australia New Zealand. In September 2008 another application was received from Healthy Workplace Solutions Pty Ltd, trading as HealthySleep Solutions for the assessment of unattended sleep studies. Both applications were considered in the one assessment.

Eight items are currently listed on the Medicare Benefits Schedule (MBS) to reimburse medical services associated with sleep study investigation of sleep apnoea. Level 1 sleep studies are currently publicly funded, while Level 2 sleep studies are the only unattended sleep studies to receive funding, albeit interim funding, on the MBS (item number 12250). This item number was listed on an interim basis on the MBS on 1 October 2008 pending MSAC's assessment.

This assessment considers whether MBS funding for unattended sleep studies for the diagnosis and reassessment of obstructive sleep apnoea (OSA) should continue and be extended to other types of sleep studies.

2. Background

OSA occurs when an upper airway blockage is experienced by a person during sleep, usually as a consequence of relaxation of the tongue and soft tissues that occlude an abnormally narrow upper airway. This narrowing is often associated with obesity in adults or developmental or congenital abnormalities in children. The affected person can suffer a repeating cycle of sleep, obstructive choking and a gasping arousal from sleep. Different types of studies are used to identify whether sleep apnoea is occurring, and to what extent, in persons presenting with symptoms of excessive daytime sleepiness, snoring, and choking or gasping during sleep as reported by the individual or an observer.

Sleep studies are categorised into four types. The Level 1 sleep study, which is also called laboratory-based polysomnography (PSG), is the gold standard in the diagnosis and reassessment of OSA. It is an 'attended' sleep study involving a laboratory technician monitoring the patient and the environment during testing. As such, it is a resource- and time-intensive procedure that results in long waiting lists. Level 2, 3 and 4 sleep studies are all 'unattended' and are usually carried out in the home.

The amount of information recorded in a sleep study reduces as the level of the sleep study increases. Both Level 1 and Level 2 sleep studies record signals that allow the reliable identification of body position, sound and arousals from sleep (eg. electrooculogram, electroencephalogram, electromyography). Whereas a Level 1 sleep study routinely involves 12 to 13 recording channels, an unattended Level 2 sleep study usually maintains a minimum of seven recording channels. In contrast, a Level 3 sleep study measures four or more parameters, including at least two respiratory channels (eg one airflow channel plus one respiratory effort channel or two airflow channels). A Level 4 sleep study is a sleep investigation where either the number or the type of cardiorespiratory signals fails to fulfil criteria for a Level 3 sleep study. A large number of sleep study devices have obtained Therapeutic Goods Administration (TGA) marketing approval and are currently used in clinical practice in Australia.

Clinical diagnosis of OSA requires confirmation using an appropriate sleep study. OSA is currently treated using a range of therapies, including continuous positive airway pressure (CPAP), ear, nose and throat (ENT) surgery, oral appliances and weight loss. CPAP is recognised as the standard treatment for OSA in adults, while ENT surgery is usually offered to children with OSA.

Public funding of home-based sleep studies is sought for patients where the pre test probability of sleep apnoea is high and/or where the patient is remote from a sleep laboratory. The applicants anticipate that the availability of home-based sleep studies will reduce demand for laboratory based sleep studies.

The following four clinical pathways were assessed in order to define the place of unattended sleep studies in OSA:

1. diagnosis in non-specialised unit
2. diagnosis in referral setting
3. diagnosis and reassessment in paediatric setting
4. reassessment in adult setting.

3. Clinical need

OSA has been associated with an increased risk of hypertension and cardiovascular events such as stroke and myocardial infarction. Available literature suggests that moderate to severe OSA in men is associated with an elevated risk of all-cause mortality, as well as death related to coronary artery disease. The OSA symptoms of excessive daytime sleepiness, headache, depression, fatigue, and difficulty in thinking and functioning due to sleep deprivation have also been associated with motor vehicle accidents and work-related accidents. OSA has also been cited as a cause of behavioural problems and learning difficulties in children. MSAC noted it was difficult to quantify these effects.

MSAC also noted that it was difficult to define the prevalence of OSA but accepted that in Australia approximately 20% of the population suffered mild OSA and approximately 5% suffered moderate to severe OSA.

MSAC noted the increase in prevalence of sleep apnoea over the period 1998–2007, Age and obesity are two risk factors for OSA and hence this trend will probably continue. The majority of people who are hospitalised for OSA are those aged 45–64 years, with peak hospitalisation occurring in the 55–59 years age group. A large cluster of hospitalisations for OSA also occurs in children aged 1–4 years.

MSAC noted significant waiting times for a Level 1 sleep study for adults, but waiting times for children are much less. MSAC questioned the utility and safety of home based studies for children given the difficulties related to managing the technology.

MSAC noted utilisation data for both the existing sleep study MBS items and the interim funded unattended sleep study MBS item and discussed the emerging trends, patterns of costs and usage of these items. The uptake of home based Level 2 studies has not been matched by a decline in use of Level 1 studies. Reasons for this were canvassed.

4. Comparator

MSAC noted that only Level 1 sleep studies can accurately determine the apnoea/hypopnea index (AHI), which is the number of apneic and hypopneic episodes per hour of sleep. This index correlates with disease severity and hence represents the gold standard.

MSAC agreed that the appropriate comparator used depends on the clinical pathway for the setting or the reassessment, however the Level 1 sleep study with or without a sleep physician was the comparator used. MSAC also noted that diagnosis involves clinical assessment followed by a sleep study and that the MBS provides funding for laboratory based sleep studies; a first-class investigation (gold standard) necessary for subtle clinical presentations.

MSAC questioned whether the new unattended sleep studies would replace or instead add to the demand for Level 1 sleep studies. This is an important consideration as the sponsors argue that there is need for home based studies because of unmet demand for Level 1 studies. MSAC also noted that Level 1 sleep studies have not been assessed by MSAC.

5. Safety

MSAC found there was minimal evidence available to assess the safety of unattended sleep studies. MSAC noted that expert opinion suggests there is a risk of ill-fitting a CPAP mask in children, however it was assumed that for adults the safety of Levels 2, 3 and 4 sleep studies was no worse than Level 1 sleep studies. Overall, unattended sleep studies were considered by MSAC to be safe.

6. Clinical effectiveness

MSAC discussed the clinical effectiveness of unattended sleep studies for diagnosing OSA according to their use in specific health care settings. MSAC acknowledged that the more factors that are measured, the more accurate the sleep study test.

MSAC noted there was poor quality evidence from uncontrolled trials in non specialised setting. MSAC also noted that clinical effectiveness of unattended sleep studies suggested improved health outcomes, although the quality of life did not appear to improve. There were no comparative studies for unattended sleep studies relative to attended sleep studies (Level 1) and that this situation was unlikely to change given the range or timing of treatment options.

Diagnosis in a non-specialised unit setting

MSAC considered that the limited nature of the direct evidence and the lack of comparative data made it difficult to conclude that unattended sleep studies would be as, or more, effective than referral to a sleep physician or use of a Level 1 sleep study at improving the health outcomes of patients, based on direct evidence alone.

Diagnosis in a referral setting

MSAC acknowledged that the evidence base indicates that use of unattended sleep studies will result in a change in patient management. In the situation where all patients would normally receive a Level 1 sleep study, approximately 60% of patients would not receive further testing after an unattended sleep study. MSAC noted that the use of unattended sleep studies would therefore result in an earlier diagnosis of OSA; this time difference, although not clinically relevant, might be significant from a patient's point of view.

Diagnosis in a paediatric setting

MSAC acknowledged there was a lack of comparative evidence and sparse linked evidence to indicate the effectiveness of unattended sleep studies for this patient population, relative to Level 1 sleep studies. MSAC acknowledged that the cost of unnecessary surgery or therapy in children negated the benefits of unattended studies.

Reassessment of treatment efficacy

MSAC noted there was no available evidence with which to assess the effectiveness of unattended sleep studies for reassessing treatment efficacy.

7. Cost-effectiveness

A cost comparison analysis of the proposed diagnostic approach (use of unattended sleep studies) relative to the current clinical pathway (use of laboratory based PSG) was undertaken and subjected to sensitivity analysis.

MSAC noted the potential for cost savings in non-specialised and referral settings for adults, but there would be additional costs incurred in the paediatric population.

Based on the above assessments of safety and clinical effectiveness compared with the comparator MSAC concluded that unattended sleep studies in the diagnosis of OSA appears to be no worse than attended Level 1 studies in improving health outcomes.

MSAC noted that the main economic issues or issues of uncertainty were that any cost savings may be cancelled if a high proportion of unattended cases go on to Level 1 sleep studies. Given that the treatment of adult OSA is lifelong CPAP it seems likely that patients who have a positive Level 2 3 or 4 sleep studies would go on to have the gold standard test before CPAP was prescribed.

MSAC noted there was also uncertainty of the costs as the estimates of unit costs for Level 3 and 4 studies were provided by the applicant.

8. Financial/budgetary impacts

MSAC agreed that the home based studies appeared cost effective in non-specialised and referral settings, but not in the paediatric setting.

MSAC considered the likely volume of utilisation of sleep studies per year based on the target population figures for each setting.

MSAC considered the total costs to society of unattended sleep studies would be between (approximately) $39 and $61 million, relative to the current diagnostic pathway, use of unattended sleep studies in a non-specialised unit setting could achieve cost savings of $5.4 to $8.2 million. Use in referral setting could achieve cost savings of $212,303 to $320,457 but use in a paediatric setting would lead to an additional societal cost of $295,051 to $702,502. MSAC noted that these estimates were very much an approximation and that the actual utilisation of the technology, if publicly funded, was unknown.

MSAC noted potential cost savings to the MBS of $4.2 million to $6.3 million for use of unattended sleep studies in non-specialised unit settings, and $225,595 to $340,521 in the referral setting when compared to laboratory based studies. MSAC found that unattended sleep studies in the paediatric setting would cost an additional $178,209 to $419,545.

MSAC carefully considered the risk of leakage of the technology to indications other than OSA. MSAC expressed concern that identified cost savings would be reduced if a high proportion of unattended sleep studies patients go on to have Level 1 sleep studies. Levels 2, 3 and 4 studies appear to be cost effective only when they *replace* Level 1 studies. Levels 2, 3 or 4 unattended sleep studies may require a Level 1 study if the test result is uncertain. Even when an unattended test provides a positive result, the risk of false positive results may mean that confirmatory Level 1 testing is done prior to prescribing CPAP therapy. For this reason utilisation estimates may be too low and the financial impact underestimated.

Other factors considered by MSAC included the costs of accreditation of laboratories and professionals and the reliability of test interpretation with patient compliance being higher with medical specialist education. MSAC also considered the technological considerations such as data loss due to sensor detachment and issues of patient access including rural and remote settings.

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

MSAC recognised the clinical relevance of this service as evidenced by the dedication and enthusiasm of sleep physicians, and their genuine concern about lack of access to Level 1 studies resulting in unmet need.

Although based on a small number of studies, MSAC found Level 2, 3 and 4 unattended sleep settings to be as safe as the currently funded Level 1 studies (which have trained staff in attendance) for obstructive sleep apnoea (OSA), except in the case of young children or patients with cognitive disorders. MSAC concluded that the more physiological parameters that are measured, the more accurate the diagnostic performance of the service, with performance decreasing from Level 1 (thirteen parameters) to Level 4 (one to two parameters) sleep studies. MSAC noted that there was little evidence correlating the diagnostic results from each level of sleep study with clinical outcomes, particularly in relation to false positive results, and that the utility of testing was directly related to judicious patient selection based on a clinical assessment of pre-test probability. MSAC noted that the economic analyses presented indicated that, when compared to laboratory-based polysomnography, public funding of all three types of unattended sleep studies for adults is likely to lead to cost savings for society and Government. However, unattended sleep studies in a paediatric setting will lead to increased costs for society and Government.

MSAC supported public funding of adult Level 2 sleep studies on a referred basis because, with seven parameters studied, 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 also noted as relevant the fact that the facilities currently available for performing Level 1 sleep studies are inadequate to meet demand for the diagnosis of OSA. However, MSAC's support for public funding of unattended sleep studies was subject to a number of caveats. Most importantly, financial impacts for Government could not be accurately determined because valid or plausible estimates of the likely uptake of the technology are lacking. Other areas of uncertainty included quality and cost implications of credentialing of sleep services, training of health professionals, appropriate patient selection, device selection and use of the service for a wider range of conditions than OSA.

MSAC did not support public funding for Levels 3 (four parameters) and 4 (one to two parameters) 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.

10. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to safety, effectiveness and cost-effectiveness, MSAC supports public funding for the use of Level 2 unattended sleep studies for investigation of obstructive sleep apnoea (OSA) for a duration of at least 8 hours, for an adult aged 18 years and over, where:

(a) the patient is referred for the investigation by a medical practitioner who has formed a reasonable clinical view that the patient has a high probability of having OSA

*[(b) the necessity for the investigation is determined by a qualified sleep medicine practitioner (as defined in the explanatory notes to the MBS) prior to the investigation;] [*referred study]

(c) a qualified sleep medicine practitioner has:

  (i) established quality assurance procedures for the data acquisition; and
  (ii) personally analysed the data and written the report;

(d) during a period of sleep, the investigation is a recording of a minimum of seven channels which must include continuous EEG, continuous ECG, airflow, thoraco-abdominal movement , oxygen saturation; and two or more of EOG, chin EMG and body position.

(e) interpretation and report of the investigation (with analysis of sleep stage, arousals, respiratory events and assessment of clinically significant alterations in heart rate) are provided by a qualified sleep medicine practitioner based on reviewing the parameters recorded under (d) above.

MSAC supports the payment of the benefit only once in a 12-month period, and recommends review of the Schedule Fee for Level 2 unattended studies in the current interim MBS item 12250 to ensure that the service remains cost-effective.

MSAC does not support public funding for Level 3 or 4 unattended sleep studies.

MSAC does not support public funding for any unattended sleep studies for diagnosis in a paediatric setting or for reassessment of treatment efficacy.

11. Context for Decision

This advice was made under the MSAC Terms of Reference:

- Advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported.
- Advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness.
- Advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures.
- Undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to the AHMAC.

12. Linkages to Other Documents

MSAC's processes are detailed on the MSAC Website at: www.msac.gov.au.

The MSAC Assessment Report is available at http://www.msac.gov.au/internet/msac/publishing.nsf/Content/completed-assessments