16 April 2020

The Honourable Greg Hunt, MP
Minister for Health
Parliament House
Canberra ACT 2600

By email: minister.hunt@health.gov.au

Dear Minister Hunt,

We write on behalf of the Board and membership of the peak sleep disorders professional society, the Australasian Sleep Association. The COVID-19 crisis has effectively shut down public and private sleep laboratories across the country, in preparation for an expected influx of COVID-19 patients. Patient access to diagnosis and treatment of sleep disorders is thus also effectively shut down. However, there is a workable alternative to laboratory-based polysomnography – home-based sleep studies.

As the current situation is likely to impact on access to sleep health care for several months to come – and for some services into next year – we propose an urgent temporary amendment to MBS sleep study item numbers, to allow ongoing access to sleep health care for all Australians. These items will complement the timely raft of telehealth item numbers already implemented, via the temporary COVID-19 arrangements.

SUMMARY

- No paediatric and few adult sleep medicine services can be performed due to COVID-19.
- However, services to the community could still be provided if tiered complexity, home-based sleep studies were supported by a temporary amendment to the existing MBS item number (12250).
- Such an amendment would allow existing home sleep study testing to be expanded temporarily to assess and treat sleep disordered breathing more broadly during this period. This would ensure access to sleep diagnostic and treatment services during the COVID-19 pandemic.

Sleep is vitally important for good health and immune function.[1] This was acknowledged in the recent (April 2019) Parliamentary Inquiry into Sleep Health Awareness in Australia[2] which produced 11 recommendations, two being directly relevant to this discussion:

1. "The Committee recommends that the Australian Government prioritise sleep health as a national priority and recognise its importance to health and wellbeing alongside fitness and nutrition."
2. "The Committee recommends that the Department of Health undertake a review of the Medicare Benefits Schedule as it relates to sleep health services in Australia. The review

should include simple diagnostic sleep studies (Level 3 and Level 4) that do not currently attract Medicare rebates."

This report also acknowledged that approximately one in five Australians are estimated to be affected by a major sleep disorder[3] including: obstructive sleep apnoea (OSA), insomnia, restless legs syndrome and others, and that sleep disorders may also contribute to other health conditions, including: diabetes, obesity, mental health and cardiovascular disease[4].

Clinical Situation Before COVID-19 pandemic

Adults

Diagnostic sleep services were delivered either through an overnight stay in a Sleep Laboratory (Level 1 supervised study, 12203) or at home (Level 2 unsupervised study, 12250). Most patients who had home studies attended the Sleep Laboratory for face to face evening setup and returned the equipment the following morning. Treatment studies to assess effectiveness of therapy were only delivered in the Sleep Laboratory (Level 1 supervised study, 12204, 12205). **On average 5,300 Level 1 studies and 6,800 Level 2 studies were performed per month in Australia in 2019** (data provided from Department of Health).

Children

All paediatric sleep studies were performed in a Sleep Laboratory (Level 1 supervised: diagnostic 12210 in children <12 years; 12213 in children 12-18 years; 12215 and 12217 treatment studies to determine the efficacy of therapy in the two age categories). **On average 900 paediatric studies were performed per month in Australia in 2019** (data provided from Department of Health).

Clinical Situation Now (April 2020) during COVID-19 pandemic

There has been a 90% reduction in sleep testing due to infection risk to staff and patients, cancellation of elective admissions in hospitals and lack of personal protective equipment (personal communication ASA members). Between February and March 2020 there has been a 40% decline in numbers of sleep studies performed (data provided by Department of Health).

Adults

All Level 1 sleep laboratory testing has ceased (or is substantially reduced). For Level 2 home diagnostic testing the preferred practice of face to face setting up of patients has ceased (or is substantially reduced).

Level 2 diagnostic sleep testing can still occur without face to face contact using mail/courier services with written, video or telehealth instructions for patient self-set up. This is within the item number description for Level 2 sleep studies (12250). Setups take up to 60 minutes per patient with application of up to 12 different sensors to the scalp, face, trunk, legs and hands. However, many vulnerable groups are unable to perform self-set ups due to limited English, age and comorbid illness, disability and lack of access to internet, phone or a safe home environment. These patients would usually be studied in a Sleep Laboratory (Level 1).

Children

All paediatric sleep laboratories have suspended (or substantially reduced) Level 1 diagnostic and treatment testing due to the infection risk associated with the unavoidable close contact to a child and parents. There are currently **NO** current item numbers to deliver home sleep studies to children. However, research increasingly demonstrates the feasibility, adequacy and diagnostic capability of full polysomnography studies conducted at home in children[5-7] and it is currently being performed in

Australia with good outcomes in a few centres (personal communication from paediatric ASA members).

The Problem: Sleep services are essential to adults and children in Australia

1. Diagnostic and treatment sleep studies must be available to those who need them.

Untreated sleep disordered breathing carries significant risk of morbidity and early mortality for all age groups[8]. Suspension or reduction of sleep testing places further delay on services and threatens to compound already excessive waiting lists (average wait time for adult studies 2-6 months; paediatric studies 6-18 months; personal communication). It is estimated that in Australia approximately 13,000 sleep studies are not currently being performed per month due to COVID-19 measures.

Children currently have no access to any sleep testing. In Australia there has never been a major need for home sleep testing in children due to the relative accessibility to laboratory-based polysomnography but this has all changed due to COVID-19. The children most at risk are those with complex disease, or sleep disordered breathing in conjunction with comorbidities. Sleep studies are essential to accurately assess disease and therapy success. The establishment of such services (whilst challenging) would enable some studies to continue during the pandemic, treating patients most at risk and reducing the likely backlog of patients waiting when they reopen. Paediatric physicians would be at the frontline to determine which families and children are suitable for such studies.

In addition, adenotonsillectomy surgery which is first line therapy for paediatric sleep apnoea is only being performed in very urgent cases due to the high risk of infection and the need to conserve personal protective equipment (PPE). However, other therapies for sleep disordered breathing can still be delivered to adults and children either without face to face contact (preferred option) or with full PPE if deemed urgent or essential (CPAP, oral appliance therapy etc) in the COVID-19 era.

The most vulnerable groups to limited access to sleep services in the Australian population are children, the elderly, those with comorbidities and disabilities, those with limited English and those in rural communities.

2. There is a major risk that many sleep services will collapse and never re-open.
At present, most sleep services are suspended. But as time goes on, it is likely that many of these services will close permanently. We are concerned that this will be a permanent blow to the sleep medicine and sleep service sectors that were already struggling to meet the community need for sleep services.

The Solution: Enabling Access to Sleep Medicine Services

1. We propose **temporary** (end of calendar 2020) amendments to existing home sleep study items to the Medicare Benefits Schedule (MBS) for **both adults and children** for those with a high likelihood of sleep disordered breathing. This would involve the use of simpler, easy to apply devices (Level 3 or 4 studies) which measure fewer parameters (minimum 1, up to 4 channels with direct assessment of oximetry, airflow, respiratory effort, body position and others) but have proven ability to confirm a diagnosis of obstructive sleep apnoea in adults[9] and children[6,10] when administered under the guidance of a sleep physician. These devices can be used without face to face set up and can be mailed to patients.

2. It is vital to retain access to the current item number for Level 2 home sleep studies (item 12250) for adults and a **temporary** amendment granted to allow children to be studied where

home testing is possible and clinically appropriate at the direction of the treating paediatric sleep physician.

3. It is vital to retain access to Level 1 laboratory sleep study item numbers to enable these studies to resume promptly when safe to do so.

4. The provision of these Level 2, 3 and 4 studies under the existing home sleep study item number empowers sleep physicians to adapt to the current COVID-19 environment in a flexible way to ensure that each patient receives the most appropriate sleep test given their own individual clinical situation.

The details regarding the temporary amendments to existing item numbers are set out in Appendix One.

We thank you for your consideration of this matter and look forward to your response.

Yours truly,

Dr Alan Young MBBS FRACP PhD
President

Dr Sutapa Mukherjee MBBS FRACP PhD
Clinical Chair

CC: Commonwealth Department of Health - Medical Specialist Services Section

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Appendix One

Detail of temporary amendments to existing item numbers

The proposed temporary amendments would be strictly limited in duration to the end of calendar 2020, when it would be reviewed by the Department of Health in consultation with the ASA and removed when no longer required (i.e. when the current restrictions as described above have been lifted and it is safe to resume Level 1 sleep studies).

These studies would be accessible **only** if they are requested following a consultation (including telehealth) with an accredited sleep medicine practitioner or respiratory physician (adult or paediatric) **and** the study raw sleep study data are reviewed and reported by an accredited sleep medicine practitioner (adult or paediatric). Note that our recommendation is that these amended item numbers should not be available through the alternative questionnaire-based pathway in the existing item number and we have sought input on this preferred model of care from the Department of Health-Medical Specialist Services Section. There would be a restriction on the number of studies permitted within the time period.

An estimate of the numbers of studies to be performed is difficult because of the constantly evolving status of COVID-19. These temporary amendments are not intended to replace Level 1 studies but merely to allow some sleep assessments to occur for those most in need. Due to the challenges of delivering home sleep testing (patient/system/resources-related) and the reduction in patients attending their doctor due to COVID-19 it is unlikely that 13,000 sleep studies could be delivered per month as per 2019 figures. However, there is capacity, capability and enthusiasm within the Australian sleep physician community to use home sleep testing in innovative ways and it might be projected that 6,500 studies could be performed each month within 3 months of approval of the item numbers.

Suggested item numbers and notes (to be modified as needed after review by Department of Health Medical Specialist Section):

12250_B Level 4 Sleep study- Home oximetry as screening for OSA
A qualified sleep medicine practitioner or respiratory physician (adult or paediatric) determines the necessity for the investigation through face-to-face or telehealth consultation prior to the investigation.

The study is performed:

- For a minimum period of 8 hours, and
- Under the supervision of a qualified sleep medicine practitioner.

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 data from the patient.

The proposed fee is matched to that of item 11503 (complex measurement of properties of the respiratory system):

- 0-12 years fee: $140.85 Paediatric Sleep Medicine Practitioner Benefit: 75% = $105.65 85% = $119.75
- 12- 18 years fee: $140.85 Paediatric Sleep Medicine Practitioner Benefit: 75% = $105.65 85% = $119.75
- Over 18 years fee: $140.85 Paediatric or Adult Sleep Medicine Practitioner Benefit: 75% = $105.65 85% = $119.75

12250_C Level 3 Sleep Study- Limited channel sleep study for diagnosis of OSA or treatment initiation or effectiveness assessment at home

An accredited sleep medicine practitioner or respiratory physician (adult or paediatric) determines the necessity for the investigation prior to the investigation, through face-to-face or telehealth consultation. This is intended for children or adults with complex OSA (comorbidities or other diagnoses) for diagnosis or to cater for treatment assessment (initiation or effectiveness). Therapy institution of CPAP or NIV therapy in children or adults, OR to monitor children or adults already on therapy (CPAP/NIV, oxygen therapy, weight loss, positional therapy, oral appliances).

The study is performed:

- For a minimum period of 8 hours, and
- under the supervision of a qualified sleep medicine practitioner.
-

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 data from the patient.

The proposed fee is 20% less than that proposed for home polysomnography as detailed below:

- 0-12 years fee $324.20 Paediatric Sleep Medicine Practitioner Benefit: 75%=$243.15, 85% = $275.57
- 12-18 years fee $292.92 Paediatric Sleep Medicine Practitioner 75% = 219.69, 85% = $248.98
- Over 18 years fee $292.92 Paediatric or Adult Sleep Medicine Practitioner 75% = 219.69, 85% = $248.98

12250_D Level 2 Sleep study for children – Polysomnography at home

A qualified paediatric sleep medicine practitioner determines the necessity for the investigation through face-to-face or telehealth consultation prior to the investigation for the diagnostic and monitoring purpose of paediatric sleep disordered breathing.

The study is performed:

- For a minimum period of 8 hours, and
- Under the supervision of a qualified sleep medicine practitioner.

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 data from the patient.

Same criteria as for a full polysomnography at home +/- transcutaneous carbon dioxide monitoring.

The proposed fee is calculated as 57% of in-laboratory rebates (to match ratio of adult in-laboratory to home studies):

- 0-12 years fee $406.45 Paediatric Sleep Medicine Practitioner (75% = $304.86, 85% = $358.19)
- 12- 18 years fee $366.17 Paediatric Sleep Medicine Practitioner (75% = $274.63, 85% = $317.89)