EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

Health Insurance Act 1973

Health Insurance (Section 3C General Medical Services – Vigilance Testing) Determination 2018

Subsection 3C(1) of the *Health Insurance Act 1973* (the Act) provides that the Minister may, by legislative instrument, determine that a health service not specified in an item in the general medical services table shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the general medical services table.

The general medical services table is set out in the regulations made under subsection 4(1) of the Act, and is repealed and remade each year.

Purpose

Six new items will be introduced to provide ongoing benefits for vigilance testing for the assessment of excessive daytime sleepiness, for adults and children, from 1 November 2018. Vigilance testing is primarily required to assess patient eligibility for certain medicines for narcolepsy listed on the Pharmaceutical Benefits Scheme (PBS).

Currently, vigilance testing is performed by claiming a combination of items for the daytime and night-time component of the service:

- 12203 (overnight adult sleep study) followed by 11003 (daytime electroencephalography component) for adults; or
- 12210 or 12213 (overnight paediatric sleep studies) followed by 11003 for children.

The six new items provide a service for both the daytime and the night-time component of vigilance testing. Services provided under the new items are for a multiple sleep latency test for the assessment of unexplained hypersomnolence, and for the maintenance of wakefulness test for the assessment of the ability to maintain wakefulness, for three age cohorts:

- adults (patients aged 18 years or more);
- patients aged at least 12 years but less than 18 years; and
- children (patients aged less than 12 years).

The daytime component includes monitoring of the patient, during which there is continuous recording of electro-encephalogram (EEG), electro-myogram (EMG), electro-oculogram (EOG) and electro-cardiogram (ECG).

The new items for vigilance testing, which have fees equivalent to the sum of the existing combination of items, have been assessed and recommended by the Medical Services Advisory Committee.

The purpose of the *Health Insurance (Section 3C General Medical Services – Vigilance Testing) Determination 2018* (the Determination) is to implement these six new items (12254, 12258, 12261, 12265, 12268 and 12272).

Consultation

MSAC and its Executive reviews new or existing medical services or technology, and the circumstances under which public funding should be supported. This includes the listing of new items, or amendments to existing items on the Medicare Benefits Schedule.

As part of the MSAC process, targeted consultation was undertaken with:

- Thoracic Society of Australia and New Zealand
- Royal Australasian College of Physicians
- Sleep Health Foundation
- Hypersomnolence Australia and Sleep Disorders Australia
- CRC Alertness, Safety and Productivity

Details of the Determination are set out in the Attachment.

The Determination commences on 1 November 2018.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

<u>Authority</u>: Subsection 3C(1) of the *Health Insurance Act 1973*

ATTACHMENT

Details of the *Health Insurance (Section 3C General Medical Services – Vigilance Testing)* Determination 2018

Section 1 - Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C General Medical Services – Vigilance Testing) Determination 2018.*

Section 2 - Commencement

Section 2 provides that the Determination commences on 1 November 2018.

Section 3 – Authority

Section 3 provides that the Determination is made under subsection 3C(1) of the *Health Insurance Act 1973*.

Section 4 – Definitions

Section 4 defines terms used in the Determination.

Section 5 – Treatment of relevant services

Section 5 provides that a clinically relevant service provided in accordance with the Determination shall be treated, for relevant provisions of the *Health Insurance Act 1973* and *National Health Act 1953*, and regulations made under those Acts, as if it were both a professional service and a medical service and as if there were an item specified in the general medical services table for the service.

Section 6 – Application of provisions of the general medical services table

Subsection 6(1) provides that items 12254, 12258, 12261, 12265, 12268 and 12272 may be provided by a person other than a medical practitioner.

Subsection 6(2) provides that for items 12261 and 12265, a qualified sleep medicine practitioner means a qualified adult sleep medicine practitioner or a qualified paediatric sleep medicine practitioner.

Subsection 6(3) provides that for items 12268 and 12272, a qualified sleep medicine practitioner means a qualified paediatric sleep medicine practitioner. It does not include a qualified adult sleep medicine practitioner.

Subsection 6(4) provides that for items 12254 and 12258, a qualified sleep medicine practitioner means a qualified adult sleep medicine practitioner. It does not include a qualified paediatric sleep medicine practitioner.

Schedule – Relevant services

The Schedule lists items 12254, 12258, 12261, 12265, 12268 and 12272.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

Health Insurance (Section 3C General Medical Services – Vigilance Testing) Determination 2018

This Determination is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny)* Act 2011.

Overview of the Determination

Six new items will be introduced to provide ongoing benefits for vigilance testing for the assessment of excessive daytime sleepiness, for adults and children, from 1 November 2018. Vigilance testing is primarily required to assess patient eligibility for certain medicines for narcolepsy listed on the Pharmaceutical Benefits Scheme (PBS).

Currently, vigilance testing is performed by claiming a combination of items for the daytime and night-time component of the service:

- 12203 (overnight adult sleep study) followed by 11003 (daytime electroencephalography component) for adults; or
- 12210 or 12213 (overnight paediatric sleep studies) followed by 11003 for children.

The six new items provide a service for both the daytime and the night-time component of vigilance testing. Services provided under the new items are for a multiple sleep latency test for the assessment of unexplained hypersomnolence, and for the maintenance of wakefulness test for the assessment of the ability to maintain wakefulness, for three age cohorts:

- adults (patients aged 18 years or more);
- patients aged at least 12 years but less than 18 years; and
- children (patients aged less than 12 years).

The daytime component includes monitoring of the patient, during which there is continuous recording of electro-encephalogram (EEG), electro-myogram (EMG), electro-oculogram (EOG) and electro-cardiogram (ECG).

The new items for vigilance testing, which have fees equivalent to the sum of the existing combination of items, have been assessed and recommended by the Medical Services Advisory Committee.

The purpose of the *Health Insurance (Section 3C General Medical Services – Vigilance Testing) Determination 2018* (the Determination) is to implement these six new items (12254, 12258, 12261, 12265, 12268 and 12272).

Human rights implications

This Determination engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the *'highest attainable standard of health'* takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The Committee reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

Analysis

This Determination will maintain and advance rights to health and social security by ensuring access to publicly subsidised health services which are clinically effective, safe and cost-effective.

Conclusion

This Determination is compatible with human rights as it has a positive effect on the right to health and the right to social security.

Michael Ryan Acting Assistant Secretary MBS Policy and Specialist Services Branch Medical Benefits Division Department of Health