

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Amendment Determination 2021

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 pathology services table (the Table) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the Table.

The Table is set out in the regulations made under section 4A of the Act. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020*.

This instrument relies on subsection 33(3) of the *Acts Interpretation Act 1901* (AIA). Subsection 33(3) of the AIA provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Purpose

The purpose of the *Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Amendment Determination 2021* (the Determination) is to amend the *Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Determination 2020* to introduce new glycosylated haemoglobin (HbA1c) point of care testing item 73826 and to clarify that a service under items 73826 to 73837 is considered a prescribed pathology service.

Under new item 73826, a participating nurse practitioner will be able to provide an HbA1c point of care test to a patient diagnosed with diabetes mellitus (diabetes) for the monitoring of diabetes. An HbA1c test provides practitioners with the patient's average blood glucose level for the preceding 3 to 4 month period. Item 73826 will assist the nurse practitioner to determine whether the patient's diabetes is appropriately controlled or whether further intervention is necessary to manage the patient's diabetes.

Currently, HbA1c testing is performed in the laboratory and requires a follow-up consultation with a medical practitioner to discuss the results. New item 73826 will allow HbA1c testing to be performed in an accredited medical practice by a participating nurse practitioner.

The listing of item 73826 onto the MBS will significantly reduce test result turn-around times, increase patient convenience, and improve service access, particularly for patients based in regional, rural and remote areas, and people with impaired mobility.

A nurse practitioner rendering a service under item 73826, must work in a general practice that is accredited by an approved accreditor against the point of care testing

accreditation module under the National General Practice Accreditation Scheme. The Scheme is administered by the Australian Commission on Safety and Quality in Health Care.

A test performed under item 73826 must use instrumentation certified under the National Glycohemoglobin Standardization Program (NGSP) with a total coefficient of variation less than 3.0% at 48 mmol/mol (6.5%). These specifications ensure appropriate instrumentation is used for point of care testing. Information on the NGSP can be found at: <http://www.ngsp.org/>, as at 1 November 2021.

A service under item 73826 may be claimed a maximum of three times in a 12 month period. A service under item 73812 also may not be claimed by a patient if a total of four other glycated haemoglobin testing items, being items 66551, 73826 and 73812, have already been provided to the patient in the last 12 months.

This is in accordance with the recommendation of the Medical Services Advisory Committee (MSAC) that point of care HbA1c testing is used for the ongoing management of patients with established diabetes on an as needed basis every three to six months to assess blood glucose control. It provides a clinically meaningful indication of diabetes status over the previous three to four months. Therefore, it is not of value to repeat the test within this timeframe.

It is expected that patients will continue to have a HbA1c laboratory test (item 66551) as part of a routine yearly health assessment. Limiting item 73812 to a maximum of three tests per patient per 12-month period will avoid duplication of HbA1c point of care testing with the HbA1c pathology test ordered within this routine yearly assessment.

The Determination also clarifies that services provided under items 73826 to 73837 are considered a prescribed pathology service. A prescribed pathology service is a pathology service which is rendered by a medical practitioner, participating midwife or a participating nurse practitioner who is also the patient's treating practitioner and is listed in the *Health Insurance (Prescribed Pathology Services) Determination 2021*.

Consultation

In March 2020, the MSAC supported the creation of a new MBS item for HbA1c point of care testing for the management and monitoring of established diabetes. Government announced its response to this recommendation in the 2021-22 Budget under the *Guaranteeing Medicare – changes to the Medicare Benefits Schedule* measure.

The National Pathology Accreditation Advisory Council, Royal Australian College of General Practitioners and the Australian Commission on Safety and Quality in Health Care have been consulted and have assisted with the development of appropriate quality assurance standards and accreditation practices.

The Royal College of Pathologists of Australasia, Australian Pathology and Public Pathology Australia were also consulted on new item 73826.

Details of the Determination are set out in the [Attachment](#).

The Determination commences on 1 November 2021.

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

Authority: Subsection 3C(1) of the
Health Insurance Act 1973

Details of the *Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Amendment Determination 2021*

Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Amendment Determination 2021*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 November 2021.

Section 3 – Authority

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

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to this Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Determination has effect according to its terms.

Schedule 1 – Amendments

Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Determination 2020

Item 1 inserts new clauses 19 and 20. New Clause 19 clarifies that a service provided under items 73826 to 73837 is a prescribed pathology service, and new clause 20 provides limitations on how often a service under item 73826 can be provided where items 66551 and 73812 of the *Health Insurance (Section 3C Pathology Services – HbA1c Point of Care Testing) Determination 2021* have also been provided in the preceding 12 month period.

New clause 19 provides that section 7 of the *Health Insurance (Prescribed Pathology Services) Determination 2021* will have effect as if a service specified in items 73826 to 73837 of Schedule 2 Part 1 were also specified in that section. As a result, items 73826 to 73837 will be a prescribed pathology service.

Under clause 20, item 73826 will not apply if the patient has received at least 4 of any of the following services in the previous 12 months: item 73812 of the *Health Insurance (Section 3C Pathology Services – HbA1c Point of Care Testing) Determination 2021*, item 66551 of the pathology services table and item 73826. This means that, for example, a patient who has already claimed item 66551 twice and item 73826 twice in the past 12 months cannot claim item 73826 again.

Item 2 inserts new item 73826, which is for the quantitation of glycated haemoglobin (HbA1c) by a participating nurse practitioner performed in the management of established diabetes. The participating nurse practitioner performing a service under item 73826 must use a method and instrument certified by the National Glycohemoglobin Standardization Program. New item 73826 will benefit patients by reducing turn-around times, increasing patient convenience, and

improving access particularly for patients based in regional, rural and remote areas, and people with impaired mobility.

A service under new item 73826 is applicable not more than three times per 12 months per patient.

Statement of Compatibility with Human Rights

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

Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Amendment Determination 2021

This instrument 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

The purpose of the *Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Amendment Determination 2021* (the Determination) is to amend the *Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Determination 2020* to introduce new glycosylated haemoglobin (HbA1c) point of care testing item 73826 and to clarify that a service under items 73826 to 73837 is considered a prescribed pathology service.

Under new item 73826, a participating nurse practitioner will be able to provide an HbA1c point of care test to a patient diagnosed with diabetes mellitus (diabetes) for the monitoring of diabetes. An HbA1c test provides practitioners with the patient's average blood glucose level for the preceding 3 to 4 month period. Item 73826 will assist the nurse practitioner to determine whether the patient's diabetes is appropriately controlled or whether further intervention is necessary to manage the patient's diabetes.

Currently, HbA1c testing is performed in the laboratory and requires a follow-up consultation with a medical practitioner to discuss the results. New item 73826 will allow HbA1c testing to be performed in an accredited medical practice by a participating nurse practitioner.

The listing of item 73826 onto the MBS will significantly reduce test result turn-around times, increase patient convenience, and improve service access, particularly for patients based in regional, rural and remote areas, and people with impaired mobility.

A nurse practitioner rendering a service under item 73826, must work in a general practice that is accredited by an approved accreditor against the point of care testing accreditation module under the National General Practice Accreditation Scheme. The Scheme is administered by the Australian Commission on Safety and Quality in Health Care.

A test performed under item 73826 must use instrumentation certified under the National Glycohemoglobin Standardization Program (NGSP) with a total coefficient of variation less than 3.0% at 48 mmol/mol (6.5%). These specifications ensure appropriate instrumentation is used for point of care testing. Information on the NGSP can be found at: <http://www.ngsp.org/>, as at 1 November 2021.

A service under item 73826 may be claimed a maximum of three times in a 12 month period. A service under item 73812 also may not be claimed by a patient if a total of four other glycosylated haemoglobin testing items, being items 66551, 73826 and 73812, have already been provided to the patient in the last 12 months.

The Determination also clarifies that services provided under items 73826 to 73837 are considered a prescribed pathology service. Generally, a prescribed pathology service is a pathology service which

is rendered by a medical practitioner, participating midwife or a participating nurse practitioner who is also the patient's treating practitioner.

Human rights implications

This instrument 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 instrument advances the right to health and the right to social security by listing a subsidised pathology service under new item 73826. This item will be used in the management of established diabetes and will significantly reduce test result turn-around times, increase patient convenience and improve service access particularly for patients based in regional, rural and remote areas and people with impaired mobility.

Conclusion

This instrument is compatible with human rights as it maintains the right to health and the right to social security.

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