

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Section 3C Pathology Services – HbA1c Point of Care Testing) 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*.

#### **Purpose**

The purpose of the *Health Insurance (Section 3C Pathology Services – HbA1c Point of Care Testing) Determination 2021* is to introduce new item 73812, which is for glycated haemoglobin (HbA1c) point of care testing, onto the Medicare Benefits Schedule (MBS) as of 1 November 2021.

Item 73812 will be used for the monitoring of diabetes mellitus (diabetes) in patients with diagnosed diabetes and will aid medical practitioners in monitoring their patient's risk of diabetes-related complications. Currently, HbA1c testing is performed in a laboratory and requires a follow-up consultation with a medical practitioner to discuss the results. New item 73812 will allow HbA1c testing to be performed in an accredited medical practice.

The listing of item 73812 onto the MBS will 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 medical practitioner rendering a service under item 73812, or the person rendering the service on behalf of the medical practitioner, must be employed 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 73812 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 73812 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 from the Medical Services Advisory Committee (MSAC) that point of care HbA1c testing should be 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.

### **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 73812.

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 Pathology Services – HbA1c Point of Care Testing) Determination 2021***

### Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Pathology Services – HbA1c Point of Care Testing) 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 – 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 a professional service and as if there were an item specified in the pathology services table for the service.

### Section 6 – Application of item 73812

Section 6 provides that section 6 of the *Health Insurance (Prescribed Pathology Services) Determination 2021* will have effect as if the service specified in item 73812 were also specified in that section. As a result, item 73812 will be a prescribed pathology service.

### Section 7 – Limitation of item 73812

Section 7 provides limitations on how often a service under item 73812 can be provided. Subsection 7(1) provides that item 73812 will not apply if the patient has received at least 4 of any of the following services in the previous 12 months: item 73812, item 66551 of the pathology services table and item 73826 of the *Health Insurance (Section 3C Midwife and Nurse Practitioner Services) Determination 2020*. This means that, for example, a patient who has already claimed item 66551 twice and item 73812 twice in the past 12 months cannot claim item 73812 again.

### Schedule – Relevant services

The Schedule specifies the service and the associated fee for item 73812.

## Statement of Compatibility with Human Rights

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

*Health Insurance (Section 3C Pathology Services – HbA1c Point of Care Testing)  
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 Pathology Services – HbA1c Point of Care Testing) Determination 2021* is to introduce new item 73812, which is for glycated haemoglobin (HbA1c) point of care testing, onto the Medicare Benefits Schedule (MBS).

Item 73812 will be used for the monitoring of diabetes mellitus (diabetes) in patients with diagnosed diabetes and will aid medical practitioners in monitoring their patient's risk of diabetes-related complications. Currently, HbA1c testing is performed in a laboratory and requires a follow-up consultation with a medical practitioner to discuss the results. New item 73812 will allow HbA1c testing to be performed in an accredited medical practice.

The listing of this MBS item aims to 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 medical practitioner rendering a service under item 73812, or the person rendering the service on behalf of the medical practitioner, must be employed in a general practice that is accredited against the point of care testing accreditation module under the National General Practice Accreditation Scheme.

A test performed under item 73812 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 73812 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 four other glycated haemoglobin testing items, being item 66551, item 73826 and item 73812, have already been provided to the patient in the last 12 months.

### 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 used in the management of established diabetes which 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 advances the right to health and the right to social security.

**Travis Haslam**  
**Acting First Assistant Secretary**  
**Medical Benefits Division**  
**Health Resourcing Group**  
**Department of Health**