

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (HbA1c Test for Diagnosis of Diabetes) Determination 2014

Subsection 3C(1) of the *Health Insurance Act 1973* (the Act) provides that the Minister may determine in writing 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 so specified. The Table is set out in the *Health Insurance (Pathology Services Table) Regulation* (the Regulation), which is re-made each year.

The purpose of the *Health Insurance (HbA1c Test for Diagnosis of Diabetes) Determination 2014* (the Determination) is to create a new Medicare pathology service, item 66841. This item is for the quantitation of HbA1c (glycated haemoglobin) for the diagnosis of diabetes in asymptomatic patients at high risk.

The HbA1c test is a biochemical test that reflects the average level of glucose in the blood over a 2–3 month period by measuring the proportion of haemoglobin that has become glycosylated. This test uses a venous blood sample and does not require any preparation or specific time of the day for testing. The test (MBS item 66551) is currently used in Australian clinical practice to monitor blood glucose in people with diabetes. There are two blood glucose measures for diagnosis of diabetes currently listed on the MBS; the fasting plasma glucose (FPG; item 66500) test and the oral glucose tolerance test (OGTT; item 66542), both of which require patients to fast beforehand. The HbA1c test is intended as an alternative to these tests in the diagnostic pathway for the majority of the population.

Consultation

An application requesting MBS listing of HbA1c testing for the diagnosis of diabetes mellitus (diabetes) was received from the Australian Diabetes Society, the Royal College of Pathologists of Australasia and the Australasian Association of Clinical Biochemists by the Department of Health in May 2012. The application was considered by the Medical Services Advisory Committee (MSAC) in April 2014. MSAC considered that access to HbA1C testing for diabetes diagnosis was clinically relevant and would provide a safe, effective and cost effective alternative to conventional testing and would improve patient compliance and early detection of diabetes. Therefore, MSAC recommended that public funding be supported for this service.

The Determination commences on 1 November 2014.

This Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Statement of Compatibility with Human Rights

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

Health Insurance (HbA1c Test for Diagnosis of Diabetes) Determination 2014

This Legislative 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 Legislative Instrument

The *Health Insurance (HbA1c Test for Diagnosis of Diabetes) Determination 2014* (the Determination) creates a new Medicare pathology service (item 66841) for the quantitation of HbA1c (glycated haemoglobin) for the diagnosis of diabetes in asymptomatic patients at high risk.

Human rights implications

This Determination engages Articles 2, 9 and 12 and 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 has also stated that the ‘highest attainable standard of health’ takes into account the country’s available resources. The 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 realization of the highest attainable standard of health.

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.

Analysis

The Determination will advance the human rights to health and social security by enabling the payment of Commonwealth Medicare benefit to assist private patients with financial costs associated with receiving these clinically relevant medical services. There are no limitations on access to new item 66841 based on grounds such as the sex, age or race of the patient.

Conclusion

This Determination is compatible with the human rights recognised in the *Human Rights (Parliamentary Scrutiny) Act 2011*.

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