

## EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Section 3C General Medical Services – Blue Light Cystoscopy)  
Determination 2019*

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.

### **Purpose**

The purpose of the *Health Insurance (Section 3C General Medical Services – Blue Light Cystoscopy) Determination 2019* (the Determination) is to list four cystoscopy Medicare Benefits Schedule (MBS) services for the diagnosis, treatment and management of non-muscle invasive bladder cancer from 1 May 2019.

Currently, patients can access cystoscopy services to detect and remove bladder tumours and lesions. The procedure is known as a white light cystoscopy (WLC), as it uses white light to detect the abnormalities. Items 36836 and 36812 are for the identification and diagnosis of bladder tumours and lesions. Items 36840 and 36845 are therapeutic services for the treatment of identified abnormalities.

In March 2018, the Medical Services Advisory Committee (MSAC) supported public funding through the MBS of blue light cystoscopy (BLC) with hexaminolevulinate (HAL) as an adjunct to standard WLC for the diagnosis, treatment and management of non-muscle invasive bladder cancer (MSAC assessment 1460). BLC uses an optical imaging agent (HAL) which causes cancerous cells to glow pink under blue light. When supplemented with WLC, it can improve the detection of bladder tumours and lesions in some patients with non-muscle invasive bladder cancer.

The four new items combine BLC with HAL and WLC as a complete cystoscopy service. Items 36504 and 36505 provide access to investigative services, and items 36507 and 36508 are therapeutic services for the treatment of identified lesions and tumours. The new items cannot be co-claimed with the standard WLC items.

The Government agreed to this MSAC decision in the 2018-19 Mid-Year Economic and Fiscal Outlook under the *Guaranteeing Medicare – strengthening primary care* measure.

### **Consultation**

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

As part of the MSAC process, public consultation was undertaken with key stakeholders on the new services for BLC with HAL as an adjunct to standard WLC for the diagnosis, treatment and management of non-muscle invasive bladder cancer.

Details of the Determination are set out in the Attachment.

The Determination commences on 1 May 2019.

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 General Medical Services – Blue Light Cystoscopy) Determination 2019***

### Section 1 – Name

Section 1 provides for the instrument to be referred to as the *Health Insurance (Section 3C General Medical Services – Blue Light Cystoscopy) Determination 2019*.

### Section 2 – Commencement

Section 2 provides that the instrument commences on 1 May 2019.

### Section 3 – Authority

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

### Section 4 – Definitions

Section 4 defines terms used in the instrument.

### 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 items 36504, 36505, 36507 and 36508

Section 6 specifies provisions of the general medical services table that apply in relation to items 36504, 36505, 36507 and 36508 contained in Schedule 1 to the instrument.

Subsection 6(1) provides that clauses 1.2.5 and 1.2.6 of the general medical services table apply to items 36504, 36505, 36507 and 36508. These clauses require a medical practitioner to personally attend the service which must be performed on a single occasion.

Subsection 6(2) provides that clause 2.45.2 of the general medical services table applies to items 36504, 36505, 36507 and 36508. Clause 2.45.2 provides that a service, provided in an item in Group T8, does not apply if the service is provided at the same time as, or in connection with, the provision of a pain pump for post- surgical pain management.

### Schedule 1 – Relevant services

The Schedule specifies the service and the associated fees for items 36504, 36505, 36507 and 36508.

## 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 – Blue Light Cystoscopy) Determination 2019***

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 General Medical Services – Blue Light Cystoscopy) Determination 2019* (the Determination) is to list four cystoscopy Medicare Benefits Schedule (MBS) services for the diagnosis, treatment and management of non-muscle invasive bladder cancer from 1 May 2019.

Currently, patients can access cystoscopy services to detect and remove bladder tumours and lesions. The procedure is known as a white light cystoscopy (WLC), as it uses white light to detect the abnormalities. Items 36836 and 36812 are for the identification and diagnosis of bladder tumours and lesions. Items 36840 and 36845 are therapeutic services for the treatment of identified abnormalities.

In March 2018, the Medical Services Advisory Committee (MSAC) supported public funding through the MBS of blue light cystoscopy (BLC) with hexaminolevulinate (HAL) as an adjunct to standard WLC for the diagnosis, treatment and management of non-muscle invasive bladder cancer (MSAC assessment 1460). BLC uses an optical imaging agent (HAL) which causes cancerous cells to glow pink under blue light. When supplemented with WLC, it can improve the detection of bladder tumours and lesions in some patients with non-muscle invasive bladder cancer.

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#### **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 will advance rights to health and social security by expanding patient access to publicly subsidised health services which are clinically effective, safe and cost-effective.

#### **Conclusion**

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

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