

# **Statement of Principles**

## concerning

# MALIGNANT NEOPLASM OF THE BREAST (Balance of Probabilities)

# (No. 85 of 2023)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(3) of the *Veterans' Entitlements Act 1986*.

Dated 25 August 2023.

The Common Seal of the Repatriation Medical Authority was affixed to this instrument at the direction of:

Professor Terence Campbell AM Chairperson

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#### 1 Name

This is the Statement of Principles concerning *malignant neoplasm of the breast (Balance of Probabilities)* (No. 85 of 2023).

## 2 Commencement

This instrument commences on 26 September 2023.

## 3 Authority

This instrument is made under subsection 196B(3) of the Veterans' Entitlements Act 1986.

## 4 Repeal

The Statement of Principles concerning malignant neoplasm of the breast No. 97 of 2014 (Federal Register of Legislation No. F2014L01387) made under subsections 196B(3) and (8) of the VEA is repealed.

## 5 Application

This instrument applies to a claim to which section 120B of the VEA or section 339 of the *Military Rehabilitation and Compensation Act 2004* applies.

#### 6 **Definitions**

The terms defined in the Schedule 1 - Dictionary have the meaning given when used in this instrument.

# 7 Kind of injury, disease or death to which this Statement of Principles relates

(1) This Statement of Principles is about malignant neoplasm of the breast and death from malignant neoplasm of the breast.

## Meaning of malignant neoplasm of the breast

- (2) For the purposes of this Statement of Principles, malignant neoplasm of the breast:
  - (a) means a primary malignant neoplasm arising from the epithelial cells of the breast of males and females; and
  - (b) includes:
    - (i) carcinoma in situ; and
    - (ii) Paget disease of the breast; and
  - (c) excludes:
    - (i) haematolymphoid tumours including non-Hodgkin lymphoma and Hodgkin lymphoma;

- (ii) malignant melanoma; and
- (iii) mesenchymal tumours including soft tissue sarcoma.
- (3) While malignant neoplasm of the breast attracts ICD-10-AM code C50 or D05, in applying this Statement of Principles the meaning of malignant neoplasm of the breast is that given in subsection (2).
- (4) For subsection (3), a reference to an ICD-10-AM code is a reference to the code assigned to a particular kind of injury or disease in *The International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification* (ICD-10-AM), Tenth Edition, effective date of 1 July 2017, copyrighted by the Independent Hospital Pricing Authority, ISBN 978-1-76007-296-4.

#### Death from malignant neoplasm of the breast

(5) For the purposes of this Statement of Principles, malignant neoplasm of the breast, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's malignant neoplasm of the breast.

Note: terminal event is defined in the Schedule 1 – Dictionary.

#### 8 Basis for determining the factors

On the sound medical-scientific evidence available, the Repatriation Medical Authority is of the view that it is more probable than not that malignant neoplasm of the breast and death from malignant neoplasm of the breast can be related to relevant service rendered by veterans or members of the Forces under the VEA, or members under the MRCA.

Note: MRCA, relevant service and VEA are defined in the Schedule 1 – Dictionary.

#### 9 Factors that must exist

At least one of the following factors must exist before it can be said that, on the balance of probabilities, malignant neoplasm of the breast or death from malignant neoplasm of the breast is connected with the circumstances of a person's relevant service:

 having received a cumulative equivalent dose of at least 0.5 sievert of ionising radiation to the breast at least 10 years before the clinical onset of malignant neoplasm of the breast;

Note: cumulative equivalent dose is defined in the Schedule 1 - Dictionary.

(2) taking menopausal hormone therapy for at least 2 years before the clinical onset of malignant neoplasm of the breast, and if the use of menopausal hormone therapy has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 5 years of cessation;

Note: *menopausal hormone therapy* is defined in the Schedule 1 - Dictionary.

- (3) using a combined oral contraceptive pill containing both estrogen and a progestogen:
  - (a) for a continuous period of between 2 and 5 years where:
    - (i) usage commenced at least 5 years before the clinical onset of malignant neoplasm of the breast; and
    - (ii) if usage has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 10 years of cessation; or
  - (b) for a continuous period of at least 5 years where:
    - (i) usage commenced at least 5 years before the clinical onset of malignant neoplasm of the breast; and
    - (ii) if usage has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 15 years of cessation;
- (4) taking diethylstilbestrol while pregnant before the clinical onset of malignant neoplasm of the breast;
- (5) for parous females only, inability to breast feed for a cumulative period of at least 3 months before the clinical onset of malignant neoplasm of the breast;

Note 1: The period of breastfeeding could be cumulative over a number of pregnancies. Note 2: *parous* is defined in the Schedule 1 – Dictionary.

(6) for females aged over 35 years only, being nulliparous at the time of the clinical onset of malignant neoplasm of the breast;

Note: *nulliparous* is defined in the Schedule 1 – Dictionary.

- (7) being pregnant within the 25 years before the clinical onset of malignant neoplasm of the breast;
- (8) having a first live birth after the age of 30 years or having a first fullterm pregnancy after the age of 30 years, before the clinical onset of malignant neoplasm of the breast;
- (9) for females only, having smoked tobacco products:
  - (a) in an amount of at least 15 pack-years before the clinical onset of malignant neoplasm of the breast; and
  - (b) commencing at least 5 years before the clinical onset of malignant neoplasm of the breast; and

if smoking has ceased before the clinical onset of malignant neoplasm of the breast then that onset occurred within 30 years of cessation

Note: *one pack-year* is defined in the Schedule 1 - Dictionary.

(10) for females only, consuming alcohol:

- (a) in an amount of at least 40 kilograms before the clinical onset of malignant neoplasm of the breast; and
- (b) at least 5 years before the clinical onset of malignant neoplasm of the breast; and

if consumption of alcohol has ceased before the clinical onset of malignant neoplasm of the breast, then that onset occurred within 40 years of cessation;

Note: Alcohol consumption is calculated utilising the Australian Standard of 10 grams of alcohol per standard alcoholic drink.

(11) inability to undertake any physical activity greater than 3 METs for at least 10 consecutive years within the 30 years before the clinical onset of malignant neoplasm of the breast;

Note: *MET* is defined in the Schedule 1 – Dictionary.

(12) for males and postmenopausal females only, being obese for a period of at least 5 years within the 20 years before the clinical onset of malignant neoplasm of the breast;

Note: *being obese* is defined in the Schedule 1 - Dictionary.

- (13) for death from malignant neoplasm of the breast only, for females aged 50 to 69 years, being prevented from accessing mammographic screening for malignant neoplasm of the breast in accordance with contemporary medical standards at the time, within the 10 years before the clinical onset of malignant neoplasm of the breast, and where:
  - (a) if mammographic screening has been resumed in the interim, there has been no normal test result; and
  - (b) the opportunity for subsequent appropriate mammographic screening has not been declined;
- (14) inability to obtain appropriate clinical management for malignant neoplasm of the breast.

#### **10** Relationship to service

- (1) The existence in a person of any factor referred to in section 9, must be related to the relevant service rendered by the person.
- (2) The factor set out in subsection 9(14) applies only to material contribution to, or aggravation of, malignant neoplasm of the breast where the person's malignant neoplasm of the breast was suffered or contracted before or during (but did not arise out of) the person's relevant service.

# 11 Factors referring to an injury or disease covered by another Statement of Principles

In this Statement of Principles:

- (1) if a factor referred to in section 9 applies in relation to a person; and
- (2) that factor refers to an injury or disease in respect of which a Statement of Principles has been determined under subsection 196B(3) of the VEA;

then the factors in that Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

# **Schedule 1 - Dictionary**

Note: See Section 6

## 1 Definitions

In this instrument:

being obese means:

- (a) having a Body Mass Index (BMI) of 30 or greater; or
- (b) for males, having a waist circumference exceeding 102 centimetres; or

(c) for females, having a waist circumference exceeding 88 centimetres.

Note: BMI is also defined in the Schedule 1 - Dictionary.

## *BMI* means $W/H^2$ where:

- (a) W is the person's weight in kilograms; and
- (b) H is the person's height in metres.

*cumulative equivalent dose* means the total dose of ionising radiation received by the particular organ or tissue from external exposure, internal exposure or both, apart from normal background radiation exposure in Australia, calculated in accordance with the methodology set out in *Guide to calculation of 'cumulative equivalent dose' for the purpose of applying ionising radiation factors contained in Statements of Principles determined under Part XIA of the Veterans' Entitlements Act 1986 (Cth), Australian Radiation Protection and Nuclear Safety Agency, as in force on 2 August 2017.* 

Note 1: Examples of circumstances that might lead to exposure to ionising radiation include being present during or subsequent to the testing or use of nuclear weapons, undergoing diagnostic or therapeutic medical procedures involving ionising radiation, and being a member of an aircrew, leading to increased levels of exposure to cosmic radiation.

Note 2: For the purpose of dose reconstruction, dose is calculated as an average over the mass of a specific tissue or organ. If a tissue is exposed to multiple sources of ionising radiation, the various dose estimates for each type of radiation must be combined.

*malignant neoplasm of the breast*—see subsection 7(2).

*MET* means a unit of measurement of the level of physical exertion. 1 MET = 3.5 ml of oxygen/kg of body weight per minute, or 1.0 kcal/kg of body weight per hour, or resting metabolic rate.

MRCA means the Military Rehabilitation and Compensation Act 2004.

*one pack-year* means the amount of tobacco consumed in smoking 20 cigarettes per day for a period of 1 year, or an equivalent amount of tobacco products.

Note 1: An equivalent amount of tobacco products is 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same. For pipe tobacco, cigars or combinations of multiple tobacco types, 1 gram of tobacco is considered to be equal to one cigarette.

Note 2: Pack-years are calculated by dividing the number of cigarettes smoked per day by 20 and multiplying this number by the number of years the person has smoked. For example, smoking 10

cigarettes per day for 10 years is equal to 5 pack-years, and smoking 40 cigarettes per day for 10 years is equal to 20 pack-years.

#### *relevant service* means:

- (a) eligible war service (other than operational service) under the VEA;
- (b) defence service (other than hazardous service and British nuclear test defence service) under the VEA; or
- (c) peacetime service under the MRCA.

Note: MRCA and VEA are also defined in the Schedule 1 - Dictionary.

*menopausal hormone therapy* means administration of estrogen preparations, often in combination with a progestogen, to offset a hormone deficiency following surgically induced or naturally occurring menopause.

nulliparous means having never given birth to a viable infant.

parous means having given birth to a viable infant.

*terminal event* means the proximate or ultimate cause of death and includes the following:

- (a) pneumonia;
- (b) respiratory failure;
- (c) cardiac arrest;
- (d) circulatory failure; or
- (e) cessation of brain function.

VEA means the Veterans' Entitlements Act 1986.