

Statement of Principles concerning CARDIOMYOPATHY (Reasonable Hypothesis) (No. 57 of 2024)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

Dated 21 June 2024.

Professor Terence Campbell AM Chairperson by and on behalf of The Repatriation Medical Authority

> Statement of Principles concerning Cardiomyopathy (Reasonable Hypothesis) (No. 57 of 2024) Veterans' Entitlements Act 1986

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1 Name

This is the Statement of Principles concerning *cardiomyopathy (Reasonable Hypothesis)* (No. 57 of 2024).

2 Commencement

This instrument commences on 23 July 2024.

3 Authority

This instrument is made under subsection 196B(2) of the Veterans' Entitlements Act 1986.

4 Repeal

The Statement of Principles concerning cardiomyopathy No.85 of 2015 (Federal Register of Legislation No. F2015L00917) made under subsections 196B(2) and (8) of the VEA is repealed.

5 Application

This instrument applies to a claim to which section 120A of the VEA or section 338 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 cardiomyopathy and death from cardiomyopathy.

Meaning of cardiomyopathy

- (2) For the purposes of this Statement of Principles, cardiomyopathy:
 - (a) means a heterogeneous group of acquired diseases of the heart muscle (myocardium) involving mechanical or electrical dysfunction; and
 - (b) includes:
 - (i) dilated cardiomyopathy;
 - (ii) restrictive cardiomyopathy;
 - (iii) myocarditis with persistent mechanical or electrical dysfunction;
 - (iv) hypertrophic cardiomyopathy;
 - (v) arrhythmogenic cardiomyopathy;

- (vi) hypertensive cardiomyopathy; and
- (vii) takotsubo (stress) cardiomyopathy; and
- (c) excludes:
 - (i) exercise-induced cardiac remodelling (athlete's heart);
 - (ii) myocardial abnormality caused by ischaemic heart disease or valvular disease; and
 - (iii) pericardial disease including pericarditis.

Note: *acquired diseases of the heart muscle, arrhythmogenic cardiomyopathy* and *takotsubo cardiomyopathy* are defined in the Schedule 1 - Dictionary.

- (3) While cardiomyopathy attracts ICD-10-AM codes I42, I43 or O90.3, in applying this Statement of Principles the meaning of cardiomyopathy 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 cardiomyopathy

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

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

8 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that cardiomyopathy and death from cardiomyopathy can be related to relevant service rendered by veterans, members of Peacekeeping Forces, 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 as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting cardiomyopathy or death from cardiomyopathy with the circumstances of a person's relevant service:

- (1) undergoing a course of radiotherapy for cancer, where the heart was in the field of radiation, before the clinical onset or clinical worsening;
- (2) having myocarditis before clinical onset or at the time of clinical worsening;

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- (3) having infection with *Trypanosoma cruzi* (Chagas disease) before clinical onset or clinical worsening;
- (4) having infection with human immunodeficiency virus before clinical onset or clinical worsening;
- (5) having phaeochromocytoma or paraganglioma at the time of clinical onset or clinical worsening;

Note: *paraganglioma* and *phaeochromocytoma* are defined in the Schedule 1 – Dictionary.

- (6) having infiltration of the myocardium due to:
 - (a) amyloidosis;
 - (b) iron overload (haemosiderosis); or
 - (c) sarcoidosis;

at the time of the clinical onset or clinical worsening;

Note: *iron overload* is defined in the Schedule 1 - Dictionary.

- (7) having a primary or metastatic neoplasm infiltrating the myocardium at the time of the clinical onset or clinical worsening;
- (8) having one of the following endocrine disorders:
 - (a) acromegaly;
 - (b) adrenal insufficiency;
 - (c) Cushing syndrome;
 - (d) diabetes mellitus;
 - (e) hyperthyroidism, including goitre or Graves disease that has resulted in hyperthyroidism;
 - (f) hypoparathyroidism;
 - (g) hypothyroidism, including Hashimoto thyroiditis that has resulted in hypothyroidism;
 - (h) primary hyperaldosteronism; or
 - (i) thyrotoxicosis;

at the time of clinical onset or clinical worsening;

Note: *acromegaly* and *primary hyperaldosteronism* are defined in the Schedule 1 – Dictionary.

(9) being obese at the time of clinical onset or clinical worsening;

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

- (10) having a clinically apparent nutritional deficiency involving:
 - (a) carnitine;
 - (b) niacin (pellagra);
 - (c) selenium (Keshan disease); or
 - (d) thiamine (wet beriberi);

at the time of clinical onset or clinical worsening;

- (11) having coeliac disease at the time of clinical onset or clinical worsening;
- (12) having acquired generalised lipodystrophy at the time of the clinical onset or clinical worsening;

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

- (13) having chronic renal failure at the time of clinical onset or clinical worsening as indicated by any of the following:
 - (a) a glomerular filtration rate of less than 15 mL/min/1.73 m² for a period of at least 3 months; or
 - (b) undergoing chronic dialysis for renal failure;
- (14) having cirrhosis of the liver before clinical onset or clinical worsening;
- (15) taking one of the following medications within the 3 months before clinical onset or clinical worsening:
 - (a) 5-fluorouracil (non-topical);
 - (b) alemtuzumab;
 - (c) amphotericin B;
 - (d) anagrelide;
 - (e) bevacizumab;
 - (f) cisplatin;
 - (g) clozapine;
 - (h) cobimetinib;
 - (i) cyclophosphamide;
 - (j) dasatinib;
 - (k) exogenous catecholamine;
 - (1) ifosfamide;
 - (m) imatinib;
 - (n) interferon alpha;
 - (o) isotretinoin or tretinoin;
 - (p) lithium;
 - (q) methylphenidate;
 - (r) mitomycin C;
 - (s) olanzapine;
 - (t) osimertinib;
 - (u) paclitaxel (when used in combination with doxorubicin);
 - (v) sunitinib;
 - (w) tacrolimus;
 - (x) trabectedin;
 - (y) trametinib;
 - (z) trastuzumab; or
 - (aa) zidovudine;
- (16) taking a medication that cannot be ceased or substituted in the long term and which is associated in the individual with the

development/worsening of cardiomyopathy during medication therapy; and either:

- (a) the improvement of cardiomyopathy within days or weeks of discontinuing or tapering medication therapy; or
- (b) the redevelopment/worsening of cardiomyopathy on rechallenge with the same medication; and

where the medication was being taken within the 3 months before clinical onset or clinical worsening;

(17) being treated with an anthracycline within the 25 years before clinical onset or clinical worsening;

Note: anthracycline is defined in the Schedule 1 - Dictionary.

- (18) taking chloroquine or hydroxychloroquine daily for at least the one year before clinical onset or clinical worsening;
- (19) for males only, consuming an average of at least 80 grams of alcohol per day for a continuous period of at least 5 years, before clinical onset or clinical worsening;

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

(20) for females only, consuming an average of at least 40 grams of alcohol per day for a continuous period of at least 5 years, before clinical onset or clinical worsening;

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

- (21) using one of the following illicit drugs at the time of clinical onset or clinical worsening:
 - (a) amphetamines or amphetamine derivatives, including 3, 4methylenedioxymethamphetamine (Ecstasy);
 - (b) anabolic-androgenic steroids; or
 - (c) cocaine;
- (22) being poisoned with cobalt, as demonstrated by haematological or biochemical evidence, at the time of clinical onset or clinical worsening;
- (23) being in the last trimester of pregnancy or being within the six months immediately postpartum at the time of clinical onset or clinical worsening;
- (24) undertaking intense physical activity of at least 6 METs at the time of clinical worsening;

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

(25) being a prisoner of war of Japan before clinical onset;

(26) experiencing a severe stressful event that causes an intense emotional or psychological response within the 30 days before the clinical onset or clinical worsening of takotsubo cardiomyopathy;

Note: takotsubo cardiomyopathy is defined in the Schedule 1 - Dictionary.

- (27) having:
 - (a) an injury or illness requiring admission to an intensive care unit or artificial ventilation;
 - (b) major trauma; or
 - (c) septicaemia;

within the 30 days before the clinical onset or clinical worsening of takotsubo cardiomyopathy;

Note 1: *artificial ventilation* is defined in the Schedule 1 - Dictionary.

Note 2: *takotsubo cardiomyopathy* is defined in the Schedule 1 - Dictionary.

(28) having a cerebrovascular accident (stroke) or subarachnoid haemorrhage within the 30 days before the clinical onset or clinical worsening of takotsubo cardiomyopathy;

Note: takotsubo cardiomyopathy is defined in the Schedule 1 - Dictionary.

- (29) being envenomated by a:
 - (a) bee or wasp;
 - (b) jellyfish such as the box jellyfish or *Pelagia noctiluca* (mauve stinger);
 - (c) scorpion;
 - (d) snake; or
 - (e) spider such as a funnel web spider, red back or katipō (black widow) spider;

within the 24 hours before the clinical onset or clinical worsening of takotsubo cardiomyopathy;

Note: *takotsubo cardiomyopathy* is defined in the Schedule 1 - Dictionary.

- (30) having hypertension for at least the 5 years before the clinical onset of hypertensive cardiomyopathy, or at the time of the clinical worsening of hypertensive cardiomyopathy;
- (31) inability to obtain appropriate clinical management for cardiomyopathy before clinical worsening.

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 clinical worsening aspects of the factors set out in section 9 apply only to material contribution to, or aggravation of, cardiomyopathy

where the person's cardiomyopathy 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(2) 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:

acquired diseases of the heart muscle means a disease of the heart muscle acquired during or after adolescence, and not caused by genetic mutations.

acromegaly means a chronic disease of adults resulting from excessive production of growth hormone after closure of the epiphyses.

anthracycline means a class of cell-cycle non-specific drugs used in cancer chemotherapy derived from *Streptomyces peucetius var. caesius*, and includes daunorubicin (daunomycin), doxorubicin (adriamycin), epirubicin, idarubicin, valrubicin and mitoxantrone.

arrhythmogenic cardiomyopathy means an arrhythmogenic heart muscle disorder with structural abnormalities of the myocardium and clinical presentation with arrhythmia.

artificial ventilation means a method to assist or replace spontaneous breathing, which may involve a mechanically-controlled ventilator, manually-assisted bag ventilation of an intubated patient, or expired air resuscitation.

being obese means having a Body Mass Index (BMI) of 30 or greater.

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

BMI means W/H² where:

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

cardiomyopathy—see subsection 7(2).

iron overload means an accumulation of excess iron in tissues and organs, which has been confirmed by elevated ferritin or transferrin saturation levels. Causes include haemochromatosis and blood transfusions.

lipodystrophy means a condition due to defective metabolism of fat, resulting in the absence of subcutaneous fat.

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.

paraganglioma means a neoplasm of chromaffin tissue which is associated with excess secretion of catecholamines, and is located in an extra-adrenal sympathetic ganglion.

phaeochromocytoma means a neoplasm of chromaffin tissue which is associated with excess secretion of catecholamines, and is located in the adrenal medulla.

primary hyperaldosteronism means a syndrome associated with excess production of the major adrenal mineralocorticoid, aldosterone, and commonly caused by adrenal adenoma or unilateral or bilateral adrenal hyperplasia.

relevant service means:

- (a) operational service under the VEA;
- (b) peacekeeping service under the VEA;
- (c) hazardous service under the VEA;
- (d) British nuclear test defence service under the VEA;
- (e) warlike service under the MRCA; or
- (f) non-warlike service under the MRCA.

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

takotsubo cardiomyopathy, also known as stress cardiomyopathy, means a type of acute non-ischaemic cardiomyopathy in which there is a sudden temporary weakening of the myocardium, with ballooning of the left ventricular apex and a hypercontractile left ventricular base.

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.