

Statement of Principles concerning MYOCARDITIS (Balance of Probabilities) (No. 18 of 2024)

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

Dated 22 February 2024

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 *myocarditis* (*Balance of Probabilities*) (No. 18 of 2024).

2 Commencement

This instrument commences on 26 March 2024.

3 Authority

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

4 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.

5 Definitions

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

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

(1) This Statement of Principles is about myocarditis and death from myocarditis.

Meaning of myocarditis

- (2) For the purposes of this Statement of Principles, myocarditis:
 - (a) means an inflammation of the heart muscle (myocardium); and
 - (b) excludes inflammation associated with coronary artery disease.
- (3) While myocarditis attracts ICD-10-AM codes I40, I41, I01.2, I09.0, I51.4, in applying this Statement of Principles the meaning of myocarditis 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 myocarditis

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

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

7 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 myocarditis and death from myocarditis 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.

8 Factors that must exist

At least one of the following factors must exist before it can be said that, on the balance of probabilities, myocarditis or death from myocarditis is connected 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 clinical onset or clinical worsening;
- (2) having a myocardial infection at the time of clinical onset or clinical worsening;
- (3) having a systemic viral infection within the 4 weeks before clinical onset or clinical worsening;
- (4) being infected with human immunodeficiency virus before clinical onset or clinical worsening;
- (5) having tuberculosis before clinical onset or clinical worsening;
- (6) having acute rheumatic fever at the time of clinical onset or clinical worsening;
- (7) having one of the following vasculitides:
 - (a) Behcet disease;
 - (b) eosinophilic granulomatosis with polyangiitis (Churg Strauss syndrome);
 - (c) giant cell (temporal) arteritis;
 - (d) granulomatosis with polyangiitis (Wegener granulomatosis);
 - (e) Kawasaki disease;
 - (f) polyarteritis nodosa; or
 - (g) Takayasu arteritis;

at the time of clinical onset or clinical worsening;

(8) having one of the following systemic inflammatory diseases:

- (a) antiphospholipid syndrome;
- (b) coeliac disease;
- (c) dermatomyositis;
- (d) Graves disease;
- (e) Hashimoto disease;
- (f) inflammatory bowel disease;
- (g) polymyositis;
- (h) rheumatoid arthritis;
- (i) scleroderma (progressive systemic sclerosis);
- (j) Sjögren syndrome; or
- (k) systemic lupus erythematosus;

at the time of clinical onset or clinical worsening;

- (9) having myasthenia gravis at the time of or before clinical onset or clinical worsening;
- (10) having cardiac graft acute cellular rejection at the time of clinical onset;
- (11) having a haematopoietic stem cell transplant within the 4 years before clinical onset or clinical worsening;
- (12) having a phaeochromocytoma or thymoma at the time of clinical onset or clinical worsening;
- (13) being treated with one of the following medications within the 3 months before clinical onset or clinical worsening:
 - (a) alkylating agents including cyclophosphamide;
 - (b) anthracyclines including doxorubicin, daunorubicin, idarubicin, epirubicin and mitoxantrone;
 - (c) antibiotics including penicillin, cephalosporins, tetracyclines, sulphonamides, isoniazid, and streptomycin;
 - (d) carbamazepine;
 - (e) diuretics including furosemide and thiazides;
 - (f) fluoropyrimidines including 5-fluorouracil and capecitabine;
 - (g) immune checkpoint inhibitors including atezolizumab, avelumab, cemiplimab, dostarlimab, durvalumab, ipilimumab, nivolumab, pembrolizumab, relatilimab, retifanlimab, and tremelimumab;
 - (h) mesalazine (5-aminosalicylic acid);
 - (i) methyl dopa;
 - (j) phenytoin;
 - (k) quetiapine;
 - (l) tumour necrosis factor alpha antagonists including infliximab;
- (14) being treated with clozapine within the 2 years before clinical onset or clinical worsening;

- (15) taking a medication for at least 7 days which is associated in the individual with the clinical onset of myocarditis during medication therapy; and which is associated with:
 - (a) an increase in the symptoms and signs of myocarditis during drug therapy; and
 - (b) cessation of the symptoms and signs of myocarditis within weeks of discontinuing drug therapy;
- (16) having a COVID-19 mRNA vaccine within the 4 weeks before clinical onset or clinical worsening;
- (17) having smallpox vaccine within the 4 weeks before clinical onset or clinical worsening;
- (18) using cocaine within the 3 months before clinical onset or clinical worsening;
- (19) being envenomated by a scorpion, wasp, hornet, bee, spider of the Latrodectus spp. (including red back spider, katipo spider and black widow spider) within the 24 hours before clinical onset;
- (20) being envenomated by a brown recluse spider (*Loxosceles reclusa*) within the one week before clinical onset;
- (21) ingesting wild mushrooms or toadstools within the 7 days before clinical onset;
- (22) having organophosphate poisoning or paraphenylene diamine poisoning at the time of clinical onset or clinical worsening;
- (23) having chronic lead poisoning at the time of clinical onset or clinical worsening;
- (24) having an alcohol use disorder at the time of clinical onset or clinical worsening;
- (25) inability to obtain appropriate clinical management for myocarditis before clinical worsening.

9 Relationship to service

- (1) The existence in a person of any factor referred to in section 8, must be related to the relevant service rendered by the person.
- (2) The clinical worsening aspects of factors set out in subsection 8 apply only to material contribution to, or aggravation of, myocarditis where the person's myocarditis was suffered or contracted before or during (but did not arise out of) the person's relevant service.

10 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 8 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 5

1 Definitions

In this instrument:

MRCA means the *Military Rehabilitation and Compensation Act 2004*. *myocarditis*—see subsection 6(2).

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 defined in the Schedule 1 - Dictionary.

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.