



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
DERMATOMYOSITIS
(Reasonable Hypothesis)
(No. 70 of 2022)

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

Dated 24 June 2022

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 *dermatomyositis (Reasonable Hypothesis)* (No. 70 of 2022).

2 Commencement

This instrument commences on 25 July 2022.

3 Authority

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

4 Repeal

The Statement of Principles concerning dermatomyositis No. 9 of 2014 (Federal Register of Legislation No. F2014L00008) made under subsection 196B(2) of the VEA is repealed.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 dermatomyositis and death from dermatomyositis.

Meaning of dermatomyositis

- (2) For the purposes of this Statement of Principles, dermatomyositis:

- (a) means a chronic inflammatory disease characterised by inflammatory skin changes, usually accompanied by progressive and symmetric skeletal muscle weakness; and
- (b) includes amyopathic dermatomyositis.

Note 1: Typical skin changes include a heliotrope rash, and red or violet, sometimes scaly, slightly raised papules that erupt on the finger joints or other bony extremities (Gottron papules). Typical muscle disease involves progressive and symmetrical weakness of the limb-girdle muscles, with or without dysphagia and respiratory muscle weakness.

Note 2: The diagnosis may be confirmed by elevation of serum levels of muscle-associated enzymes, biopsy, imaging or the presence of myositis-associated antibodies.

Note 3: Amyopathic dermatomyositis is a variant of dermatomyositis that is characterised by the typical skin rash but without muscle abnormalities. Clinically, amyopathic dermatomyositis may be hypomyopathic, with no objective weakness but with evidence of subclinical muscle involvement on testing, or amyopathic, with no evidence of muscle involvement on examination or testing.

Death from dermatomyositis

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

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 dermatomyositis and death from dermatomyositis 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 dermatomyositis or death from dermatomyositis with the circumstances of a person's relevant service:

- (1) taking a drug from the specified list of drugs for at least the 4 weeks before the clinical onset of dermatomyositis;
Note: *specified list of drugs* is defined in the Schedule 1 – Dictionary.
- (2) taking hydroxyurea for at least the 6 months before the clinical onset of dermatomyositis;
- (3) taking an immune checkpoint inhibitor or interferon alfa within the 1 year before the clinical onset of dermatomyositis;
Note: Examples of immune checkpoint inhibitors include ipilimumab, nivolumab, pembrolizumab and tremelimumab.
- (4) taking a drug which is associated in the individual with the clinical onset of dermatomyositis during drug therapy and either:
 - (a) the improvement of dermatomyositis within 2 months of discontinuing or tapering drug therapy; or
 - (b) the redevelopment of dermatomyositis on rechallenge with the same drug; and

where taking the drug continued for at least the 7 days before the clinical onset of dermatomyositis;

- (5) having a malignant neoplasm, other than non-melanotic malignant neoplasm of the skin, within 5 years of the clinical onset of dermatomyositis;
- (6) taking a drug from the specified list of drugs for at least the 4 weeks before the clinical worsening of dermatomyositis;

Note: *specified list of drugs* is defined in the Schedule 1 – Dictionary.

- (7) taking hydroxyurea for at least the 6 months before the clinical worsening of dermatomyositis;
- (8) taking an immune checkpoint inhibitor or interferon alfa within the 1 year before the clinical worsening of dermatomyositis;

Note: Examples of immune checkpoint inhibitors include ipilimumab, nivolumab, pembrolizumab and tremelimumab.

- (9) taking a drug which is associated in the individual with:
 - (a) the clinical worsening of dermatomyositis during drug therapy; and
 - (b) the improvement of dermatomyositis within 2 months of discontinuing or tapering drug therapy; and

where taking the drug continued for at least the 7 days before the clinical worsening of dermatomyositis;

- (10) having a malignant neoplasm, other than non-melanotic malignant neoplasm of the skin, within 5 years of the clinical worsening of dermatomyositis;
- (11) inability to obtain appropriate clinical management for dermatomyositis.

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 factors set out in subsections 9(6) to 9(11) apply only to material contribution to, or aggravation of, dermatomyositis where the person's dermatomyositis 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:

dermatomyositis—see subsection 7(2).

MRCA means the *Military Rehabilitation and Compensation Act 2004*.

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 also defined in the Schedule 1 - Dictionary.

specified list of drugs means:

- (a) 5-fluorouracil;
- (b) capecitabine;
- (c) D-penicillamine;
- (d) statins;
- (e) trastuzumab; or
- (f) tumour necrosis factor-alpha inhibitors.

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*.