



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
LOCALISED SCLEROSIS
(Balance of Probabilities)
(No. 62 of 2018)

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

Dated 22 June 2018

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

A handwritten signature in black ink, appearing to read 'N. Saunders', written over a faint, illegible stamp or watermark.

Professor Nicholas Saunders AO
Chairperson

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1 Name

This is the Statement of Principles concerning *localised sclerosis (Balance of Probabilities)* (No. 62 of 2018).

2 Commencement

This instrument commences on 23 July 2018.

3 Authority

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

4 Repeal

The Statement of Principles concerning localised sclerosis No. 67 of 2009 (Federal Register of Legislation No. F2009L03230) made under subsection 196B(3) of the VEA is repealed.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 localised sclerosis and death from localised sclerosis.

Meaning of localised sclerosis

- (2) For the purposes of this Statement of Principles, localised sclerosis (also known as localised scleroderma or morphea):
 - (a) means an autoimmune, fibrosing connective tissue disorder characterised by localised skin thickening with increased quantities of collagen; and
 - (b) excludes systemic sclerosis, graft versus host disease with dermal fibrosis, and scleroderma-like conditions (for example, lipodermatosclerosis, scleromyxoedema, eosinophilic fasciitis and chronic radiation dermatitis).

Note 1: Localised sclerosis is limited to the skin, subcutaneous tissue and underlying bone.

Note 2: Localised sclerosis typically presents with an absence of sclerodactyly, Raynaud phenomenon and nailfold capillary changes, and is not associated with major vascular symptoms or with visceral disease.

Note 3: The diagnosis of localised sclerosis is based on clinical findings, although histopathologic confirmation is sometimes needed to rule out other diseases. Serological markers for localised sclerosis include elevated levels of antinuclear antibody, anti-ssDNA antibody, anti-topoisomerase II alpha antibody and rheumatoid factor.

- (3) While localised sclerosis attracts ICD-10-AM code L94.0 or L94.1, in applying this Statement of Principles the meaning of localised sclerosis 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 localised sclerosis

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

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 localised sclerosis and death from localised sclerosis 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, localised sclerosis or death from localised sclerosis is connected with the circumstances of a person's relevant service:

- (1) being treated with a drug or a drug from a class of drugs from the specified list of drugs at the time of the clinical onset of systemic sclerosis;
- Note: *specified list of drugs* is defined in the Schedule 1 - Dictionary.
- (2) undergoing a course of therapeutic radiation for cancer, where the affected site was in the field of radiation, before the clinical onset of localised sclerosis;

- (3) being treated with a drug or a drug from a class of drugs from the specified list of drugs at the time of the clinical worsening of systemic sclerosis;

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

- (4) undergoing a course of therapeutic radiation for cancer, where the affected site was in the field of radiation, before the clinical worsening of localised sclerosis;
- (5) inability to obtain appropriate clinical management for localised sclerosis.

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(3) to 9(5) apply only to material contribution to, or aggravation of, localised sclerosis where the person's localised sclerosis 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:

localised sclerosis—see subsection 7(2).

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

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.

specified list of drugs means:

- (a) balicatib;
- (b) bleomycin;
- (c) enfuvirtide;
- (d) pemetrexed;
- (e) taxanes; or
- (f) tumour necrosis factor- α 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*.