

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

made under subsection 196B(3) of the

Veterans' Entitlements Act 1986

**Compilation No. 1**

**Compilation date:** 23 July 2018

**Includes amendments up to:** Amendment Statement of Principles concerning localised sclerosis (Balance of Probabilities) (No. 16 of 2019) (F2019L00006)

The day of commencement of this Amendment Statement of Principles concerning localised sclerosis is 23 July 2018.

**About this compilation**

**This compilation**

This is a compilation of the *Statement of Principles concerning localised sclerosis (Balance of Probabilities) (No. 62 of 2018)* that shows the text of the law as amended and in force on 23 July 2018.

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

**Uncommenced amendments**

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

**Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

**Modifications**

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

**Self‑repealing provisions**

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.



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

Contents

1 Name 3

2 Commencement 3

3 Authority 3

4 Repeal 3

5 Application 3

6 Definitions 3

7 Kind of injury, disease or death to which this Statement of Principles relates 3

8 Basis for determining the factors 4

9 Factors that must exist 4

10 Relationship to service 5

11 Factors referring to an injury or disease covered by another Statement of Principles 5

**Schedule 1 - Dictionary 6**

1 Definitions 6

1. Name

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

1. Commencement

This instrument commences on 23 July 2018.

1. Authority

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

1. 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.

1. 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.

1. Definitions

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

1. 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**

* 1. For the purposes of this Statement of Principles, localised sclerosis (also known as localised scleroderma or morphea):
		1. means an autoimmune, fibrosing connective tissue disorder characterised by localised skin thickening with increased quantities of collagen; and
		2. 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.

* 1. 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).
	2. 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**

* 1. 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.

1. 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.

1. 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 localised sclerosis;

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

* 1. 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;
	2. 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 localised sclerosis;

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

* 1. 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;
	2. inability to obtain appropriate clinical management for localised sclerosis.
1. 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.
2. 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:

* + 1. ***localised sclerosis***—see subsection 7(2).
		2. ***MRCA*** means the *Military Rehabilitation and Compensation Act 2004*.
		3. ***relevant service*** means:
			1. eligible war service (other than operational service) under the VEA;
			2. defence service (other than hazardous service and British nuclear test defence service) under the VEA; or
			3. peacetime service under the MRCA.

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

* + 1. ***specified list of drugs*** means:
			1. balicatib;
			2. bleomycin;
			3. enfuvirtide;
			4. pemetrexed;
			5. taxanes; or
			6. tumour necrosis factor-α inhibitors.
		2. ***terminal event*** means the proximate or ultimate cause of death and includes the following:
			1. pneumonia;
			2. respiratory failure;
			3. cardiac arrest;
			4. circulatory failure; or
			5. cessation of brain function.
		3. ***VEA*** means the *Veterans' Entitlements Act 1986*.

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

**Abbreviation key—Endnote 2**

The abbreviation key sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

**Misdescribed amendments**

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

|  |  |
| --- | --- |
|  | o = order(s) |
| ad = added or inserted | Ord = Ordinance |
| am = amended | orig = original |
| amdt = amendment | par = paragraph(s)/subparagraph(s) |
| c = clause(s) |  /sub‑subparagraph(s) |
| C[x] = Compilation No. x | pres = present |
| Ch = Chapter(s) | prev = previous |
| def = definition(s) | (prev…) = previously |
| Dict = Dictionary | Pt = Part(s) |
| disallowed = disallowed by Parliament | r = regulation(s)/rule(s) |
| Div = Division(s) |  |
| exp = expires/expired or ceases/ceased to have | reloc = relocated |
|  effect | renum = renumbered |
| F = Federal Register of Legislation | rep = repealed |
| gaz = gazette | rs = repealed and substituted |
| LA = *Legislation Act 2003* | s = section(s)/subsection(s) |
| LIA = *Legislative Instruments Act 2003* | Sch = Schedule(s) |
| (md) = misdescribed amendment can be given | Sdiv = Subdivision(s) |
|  effect | SLI = Select Legislative Instrument |
| (md not incorp) = misdescribed amendment | SR = Statutory Rules |
|  cannot be given effect | Sub‑Ch = Sub‑Chapter(s) |
| mod = modified/modification | SubPt = Subpart(s) |
| No. = Number(s) | underlining = whole or part not |
|  |  commenced or to be commenced |

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
| --- | --- | --- | --- |
| *Statement of Principles concerning localised sclerosis (Balance of Probabilities) (No. 62 of 2018)* | 26 June 2018F2018L00884 | 23 July 2018 |  |
| *Amendment Statement of Principles concerning localised sclerosis (Balance of Probabilities) (No. 16 of 2019)* | 2 January 2019F2019L00006 | 23 July 2018 |  |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| Subsection 9(1)……….. | am. No. 16 of 2019 |
| Subsection 9(3)……….. | am. No. 16 of 2019 |