

**Statement of Principles concerning peripheral artery disease (Balance of Probabilities) (No. 71 of 2020)**

made under subsection 196B(3) of the

Veterans' Entitlements Act 1986

**Compilation No. 1**

**Compilation date:** 19 September 2022

**Includes amendments up to:** Veterans' Entitlements (Statements of Principles—definition of "one pack-year") Amendment Determination 2022 (No. 94 of 2022) (F2022L01128)

The day of commencement of this Amendment Determination is 19 September 2022.

**About this compilation**

**This compilation**

This is a compilation of the *Statement of Principles concerning peripheral artery disease (Balance of Probabilities) (No. 71 of 2020)* that shows the text of the law as amended and in force on 19 September 2022.

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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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1. Name

This is the Statement of Principles concerning *peripheral artery disease* *(Balance of Probabilities)* (No. 71 of 2020).

1. Authority

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

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 peripheral artery disease and death from peripheral artery disease.

Meaning of **peripheral artery disease**

* 1. For the purposes of this Statement of Principles, peripheral artery disease means atherosclerosis of one or more arteries of the upper or lower limbs which causes partial or complete occlusion of those vessels and either:
		1. warrants medical treatment; or
		2. results in at least one of the following clinical manifestations:
			1. chronic limb ischaemia;
			2. critical limb ischaemia; or
			3. intermittent claudication or other exertional leg pain symptoms that restrict walking ability.

Note 1: Signs of chronic limb ischaemia typically include subcutaneous atrophy, hair loss, thickened nails, smooth and shiny skin, coolness, pallor, cyanosis and dependent rubor.

Note 2: Signs of critical limb ischaemia typically include rest pain, ulceration, gangrene and necrosis.

Note 3: This definition includes atherosclerosis of the iliac arteries.

* 1. While peripheral artery disease attracts ICD‑10‑AM code I70.2, in applying this Statement of Principles the meaning of peripheral artery disease 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 **peripheral artery disease**

* 1. For the purposes of this Statement of Principles, peripheral artery disease,in relation to a person, includes death from a terminal event or condition that was contributed to by the person's peripheral artery disease.

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 peripheral artery disease and death from peripheral artery disease 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, peripheral artery disease or death from peripheral artery disease is connected with the circumstances of a person's relevant service:

* 1. having hypertension before the clinical onset of peripheral artery disease;
	2. having diabetes mellitus before the clinical onset of peripheral artery disease;
	3. having dyslipidaemia before the clinical onset of peripheral artery disease;

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

* 1. where smoking has not permanently ceased, having smoked at least one pack-year of tobacco products before the clinical onset of peripheral artery disease;

Note: ***one pack-year*** is defined in the Schedule 1 - Dictionary.

* 1. where smoking has permanently ceased before the clinical onset of peripheral artery disease:
		1. having smoked at least five pack-years of tobacco products; or
		2. having smoked at least one pack-year but less than five pack-years of tobacco products, and the clinical onset of peripheral artery disease has occurred within 20 years of smoking cessation;

Note: ***one pack-year*** is defined in the Schedule 1 - Dictionary.

* 1. where exposure to second-hand smoke has not permanently ceased, being exposed to second-hand smoke for at least 1,000 hours before the clinical onset of peripheral artery disease;

Note: ***being exposed to second-hand smoke*** is defined in the Schedule 1 - Dictionary.

* 1. where exposure to second-hand smoke has permanently ceased before the clinical onset of peripheral artery disease:
		1. being exposed to second-hand smoke for at least 5,000 hours; or
		2. being exposed to second-hand smoke for at least 1,000 hours, but less than 5,000 hours, and the clinical onset of peripheral artery disease has occurred within five years of the last exposure to second-hand smoke;

Note: ***being exposed to second-hand smoke*** is defined in the Schedule 1 - Dictionary.

* 1. having hyperhomocysteinaemia before the clinical onset of peripheral artery disease;
	2. having chronic kidney disease before the clinical onset of peripheral artery disease;

Note: ***chronic kidney disease*** is defined in the Schedule 1 - Dictionary.

* 1. undergoing a course of therapeutic radiation for cancer, where the affected artery was in the field of radiation, before the clinical onset of peripheral artery disease;
	2. having received a cumulative equivalent dose of at least 1.0 sievert of ionising radiation to the affected artery before the clinical onset of peripheral artery disease;

Note: ***cumulative equivalent dose*** is defined in the Schedule 1 - Dictionary.

* 1. taking the tyrosine kinase inhibitors nilotinib or ponatinib before the clinical onset of peripheral artery disease;
	2. having hypertension before the clinical worsening of peripheral artery disease;
	3. having diabetes mellitus before the clinical worsening of peripheral artery disease;
	4. having dyslipidaemia before the clinical worsening of peripheral artery disease;

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

* 1. where smoking has not permanently ceased, having smoked at least one pack-year of tobacco products before the clinical worsening of peripheral artery disease;

Note: ***one pack-year*** is defined in the Schedule 1 - Dictionary.

* 1. where smoking has permanently ceased before the clinical worsening of peripheral artery disease:
		1. having smoked at least five pack-years of tobacco products; or
		2. having smoked at least one pack-year but less than five pack-years of tobacco products, and the clinical worsening of peripheral artery disease has occurred within 20 years of smoking cessation;

Note: ***one pack-year*** is defined in the Schedule 1 - Dictionary.

* 1. where exposure to second-hand smoke has not permanently ceased, being exposed to second-hand smoke for at least 1,000 hours before the clinical worsening of peripheral artery disease;

Note: ***being exposed to second-hand smoke*** is defined in the Schedule 1 - Dictionary.

* 1. where exposure to second-hand smoke has permanently ceased before the clinical worsening of peripheral artery disease:
		1. being exposed to second-hand smoke for at least 5,000 hours; or
		2. being exposed to second-hand smoke for at least 1,000 hours, but less than 5,000 hours, and the clinical worsening of peripheral artery disease has occurred within five years of the last exposure to second-hand smoke;

Note: ***being exposed to second-hand smoke*** is defined in the Schedule 1 - Dictionary.

* 1. having hyperhomocysteinaemia before the clinical worsening of peripheral artery disease;
	2. having chronic kidney disease before the clinical worsening of peripheral artery disease;

Note: ***chronic kidney disease*** is defined in the Schedule 1 - Dictionary.

* 1. undergoing a course of therapeutic radiation for cancer, where the affected artery was in the field of radiation, before the clinical worsening of peripheral artery disease;
	2. having received a cumulative equivalent dose of at least 1.0 sievert of ionising radiation to the affected artery before the clinical worsening of peripheral artery disease;

Note: ***cumulative equivalent dose*** is defined in the Schedule 1 - Dictionary.

* 1. taking the tyrosine kinase inhibitors nilotinib or ponatinib before the clinical worsening of peripheral artery disease;
	2. inability to obtain appropriate clinical management for peripheral artery disease.
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(13) to 9(25) apply only to material contribution to, or aggravation of, peripheral artery disease where the person's peripheral artery disease 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. ***abnormality of kidney structure or function*** means:
			1. having a glomerular filtration rate of less than 60 mL/min/1.73 m2; or
			2. having kidney damage, as evidenced by renal biopsy, imaging studies, albuminuria, urinary sediment abnormalities or other markers of abnormal renal function; or
			3. having had a kidney transplant.
		2. ***being exposed to second-hand smoke*** means being in an enclosed space and inhaling smoke from burning tobacco products or smoke that has been exhaled by another person who is smoking.
		3. ***chronic kidney disease*** means an abnormality of kidney structure or function that has been present for at least three months.

Note: ***abnormality of kidney structure or function*** is also defined in the Schedule 1 - Dictionary.

* + 1. ***cumulative equivalent dose*** means the total dose of ionising radiation received by the particular organ or tissue from external exposure, internal exposure or both, apart from normal background radiation exposure in Australia, calculated in accordance with the methodology set out in *Guide to calculation of 'cumulative equivalent dose' for the purpose of applying ionising radiation factors contained in Statements of Principles determined under Part XIA of the Veterans' Entitlements Act 1986 (Cth)*, Australian Radiation Protection and Nuclear Safety Agency, as in force on 2 August 2017.

Note 1: Examples of circumstances that might lead to exposure to ionising radiation include being present during or subsequent to the testing or use of nuclear weapons, undergoing diagnostic or therapeutic medical procedures involving ionising radiation, and being a member of an aircrew, leading to increased levels of exposure to cosmic radiation.

Note 2: For the purpose of dose reconstruction, dose is calculated as an average over the mass of a specific tissue or organ. If a tissue is exposed to multiple sources of ionising radiation, the various dose estimates for each type of radiation must be combined.

* + 1. ***dyslipidaemia*** means persistently abnormal blood lipid levels, diagnosed by a medical practitioner and evidenced by:
			1. a serum high density lipoprotein cholesterol level less than 1.0 mmol/L; or
			2. a serum low density lipoprotein level greater than 4.0 mmol/L; or
			3. a serum triglyceride level greater than or equal to 2.0 mmol/L; or
			4. a total serum cholesterol level greater than 5.5 mmol/L; or
			5. the regular administration of drug therapy to normalise blood lipid levels.
		2. ***MRCA*** means the *Military Rehabilitation and Compensation Act 2004*.
		3. ***one pack-year*** means the amount of tobacco consumed in smoking 20 cigarettes per day for a period of 1 year, or an equivalent amount of tobacco products.

Note 1: An equivalent amount of tobacco products is 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same. For pipe tobacco, cigars or combinations of multiple tobacco types, 1 gram of tobacco is considered to be equal to one cigarette.

Note 2: Pack-years are calculated by dividing the number of cigarettes smoked per day by 20 and multiplying this number by the number of years the person has smoked. For example, smoking 10 cigarettes per day for 10 years is equal to 5 pack-years, and smoking 40 cigarettes per day for 10 years is equal to 20 pack-years.

* + 1. ***peripheral artery disease***—see subsection 7(2).
		2. ***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. ***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.
		2. ***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 peripheral artery disease (Balance of Probabilities) (No. 71 of 2020)* | 30 October 2020F2020L01375 | 30 November 2020 |  |
| *Veterans' Entitlements (Statements of Principles—definition of "one pack-year") Amendment Determination 2022 (No. 94 of 2022)* | 26 August 2022F2022L01128 | 19 September 2022 |  |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| Section 2………………. | rep LA s 48D |
| Section 4………………. | rep LA s 48C |
| Subsection 9(4) note..... | rs No. 94 of 2022 |
| Subsection 9(5) note..... | rs No. 94 of 2022 |
| Subsection 9(16) note... | rs No. 94 of 2022 |
| Subsection 9(17) note... | rs No. 94 of 2022 |
| Schedule 1 – Dictionary – one pack-year...…….. | rs No. 94 of 2022 |