



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
PERIPHERAL ARTERY DISEASE
(Reasonable Hypothesis)
(No. 70 of 2020)

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

Dated 30 October 2020

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'.

Professor Nicholas Saunders AO
Chairperson

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	8
11	Factors referring to an injury or disease covered by another Statement of Principles.....	8
Schedule 1 - Dictionary		9
1	Definitions.....	9

1 Name

This is the Statement of Principles concerning *peripheral artery disease (Reasonable Hypothesis)* (No. 70 of 2020).

2 Commencement

This instrument commences on 30 November 2020.

3 Authority

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

4 Repeal

The Statement of Principles concerning atherosclerotic peripheral vascular disease No. 23 of 2012 (Federal Register of Legislation No. F2012L00454) made under subsections 196B(2) and (8) of the VEA is repealed.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 peripheral artery disease and death from peripheral artery disease.

Meaning of peripheral artery disease

- (2) 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:
- (a) warrants medical treatment; or
 - (b) results in at least one of the following clinical manifestations:
 - (i) chronic limb ischaemia;
 - (ii) critical limb ischaemia; or
 - (iii) 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.

- (3) 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).
- (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 peripheral artery disease

- (5) 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.

8 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that peripheral artery disease and death from peripheral artery disease 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 peripheral artery disease or death from peripheral artery disease 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) being obese for at least five years within the 20 years before the clinical onset of peripheral artery disease;

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

- (4) having dyslipidaemia before the clinical onset of peripheral artery disease;

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

- (5) 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: *pack-year of tobacco products* is defined in the Schedule 1 - Dictionary.

- (6) where smoking has permanently ceased before the clinical onset of peripheral artery disease:

- (a) having smoked at least five pack-years of tobacco products; or
- (b) 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: *pack-year of tobacco products* is defined in the Schedule 1 - Dictionary.

- (7) 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.

- (8) where exposure to second-hand smoke has permanently ceased before the clinical onset of peripheral artery disease:

- (a) being exposed to second-hand smoke for at least 5,000 hours; or
- (b) 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.

- (9) having hyperhomocysteinaemia before the clinical onset of peripheral artery disease;

- (10) an inability to undertake any physical activity greater than three METs for at least five years within the 20 years before the clinical onset of peripheral artery disease;

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

- (11) having chronic kidney disease before the clinical onset of peripheral artery disease;

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

- (12) 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;

- (13) having received a cumulative equivalent dose of at least 0.5 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.

- (14) an inability to consume an average of at least 100 grams per day of any combination of fruit and vegetables, for at least five consecutive years within the 20 years before the clinical onset of peripheral artery disease;

- (15) having periodontitis for at least the two years before the clinical onset of peripheral artery disease;

- (16) having an autoimmune disease before the clinical onset of peripheral artery disease;

Note: Examples of autoimmune diseases include systemic lupus erythematosus, psoriasis and rheumatoid arthritis.

- (17) having a clinically significant depressive disorder for at least five years before the clinical onset of peripheral artery disease;

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

- (18) taking the tyrosine kinase inhibitors nilotinib or ponatinib before the clinical onset of peripheral artery disease;

- (19) having hypertension before the clinical worsening of peripheral artery disease;

- (20) having diabetes mellitus before the clinical worsening of peripheral artery disease;

- (21) being obese for at least five years within the 20 years before the clinical worsening of peripheral artery disease;

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

- (22) having dyslipidaemia before the clinical worsening of peripheral artery disease;

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

- (23) 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: *pack-year of tobacco products* is defined in the Schedule 1 - Dictionary.

- (24) where smoking has permanently ceased before the clinical worsening of peripheral artery disease:
- (a) having smoked at least five pack-years of tobacco products; or
 - (b) 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: *pack-year of tobacco products* is defined in the Schedule 1 - Dictionary.
- (25) 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.
- (26) where exposure to second-hand smoke has permanently ceased before the clinical worsening of peripheral artery disease:
- (a) being exposed to second-hand smoke for at least 5,000 hours; or
 - (b) 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.
- (27) having hyperhomocysteinaemia before the clinical worsening of peripheral artery disease;
- (28) an inability to undertake any physical activity greater than three METs for at least five years within the 20 years before the clinical worsening of peripheral artery disease;
- Note: *MET* is defined in the Schedule 1 - Dictionary.
- (29) having chronic kidney disease before the clinical worsening of peripheral artery disease;
- Note: *chronic kidney disease* is defined in the Schedule 1 - Dictionary.
- (30) 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;
- (31) having received a cumulative equivalent dose of at least 0.5 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.

- (32) an inability to consume an average of at least 100 grams per day of any combination of fruit and vegetables, for at least five consecutive years within the 20 years before the clinical worsening of peripheral artery disease;
- (33) having periodontitis for at least the two years before the clinical worsening of peripheral artery disease;
- (34) having an autoimmune disease before the clinical worsening of peripheral artery disease;
Note: Examples of autoimmune diseases include systemic lupus erythematosus, psoriasis and rheumatoid arthritis.
- (35) having a clinically significant depressive disorder for at least five years before the clinical worsening of peripheral artery disease;
Note: *clinically significant* is defined in the Schedule 1 - Dictionary.
- (36) taking the tyrosine kinase inhibitors nilotinib or ponatinib before the clinical worsening of peripheral artery disease;
- (37) inability to obtain appropriate clinical management for peripheral artery disease.

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(19) to 9(37) 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.

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:

abnormality of kidney structure or function means:

- (a) having a glomerular filtration rate of less than 60 mL/min/1.73 m²; or
- (b) having kidney damage, as evidenced by renal biopsy, imaging studies, albuminuria, urinary sediment abnormalities or other markers of abnormal renal function; or
- (c) having had a kidney transplant.

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.

being obese means having a Body Mass Index (BMI) of 30 or greater.

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

BMI means W/H^2 where:

- (a) W is the person's weight in kilograms; and
- (b) H is the person's height in metres.

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.

clinically significant means sufficient to warrant ongoing management, which may involve regular visits (for example, at least monthly), to a psychiatrist, counsellor or general practitioner.

Note: To warrant ongoing management does not require that any actual management was received or given for the condition.

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.

dyslipidaemia means persistently abnormal blood lipid levels, diagnosed by a medical practitioner and evidenced by:

- (a) a serum high density lipoprotein cholesterol level less than 1.0 mmol/L; or
- (b) a serum low density lipoprotein level greater than 4.0 mmol/L; or
- (c) a serum triglyceride level greater than or equal to 2.0 mmol/L; or
- (d) a total serum cholesterol level greater than 5.5 mmol/L; or
- (e) the regular administration of drug therapy to normalise blood lipid levels.

MET means a unit of measurement of the level of physical exertion. 1 MET = 3.5 ml of oxygen/kg of body weight per minute or, 1.0 kcal/kg of body weight per hour, or resting metabolic rate.

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

pack-year of tobacco products means:

- (a) 20 cigarettes per day for a period of one calendar year; or
- (b) 7,300 cigarettes in a period of one calendar year; or
- (c) 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same, in a period of one calendar year.

peripheral artery disease—see subsection 7(2).

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.

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*.