



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
OSTEONECROSIS
(Balance of Probabilities)
(No. 14 of 2020)

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

Dated 28 February 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

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1 Name

This is the Statement of Principles concerning *osteonecrosis (Balance of Probabilities)* (No. 14 of 2020).

2 Commencement

This instrument commences on 23 March 2020.

3 Authority

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

4 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.

5 Definitions

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

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

- (1) This Statement of Principles is about osteonecrosis and death from osteonecrosis.

Meaning of osteonecrosis

- (2) For the purposes of this Statement of Principles, osteonecrosis:
 - (a) means a disease of bone where death of bone tissue occurs as a result of the temporary or permanent loss of blood supply to bone; and
 - (b) includes dysbaric osteonecrosis.

Note: Osteonecrosis is also known as avascular necrosis, aseptic necrosis or ischaemic necrosis.

- (3) While osteonecrosis attracts ICD-10-AM code K10.2, M87, M90.3, M90.4 or M90.5, in applying this Statement of Principles the meaning of osteonecrosis 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 osteonecrosis

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

Note: *terminal event* is defined in the Schedule 1 – Dictionary.

7 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 osteonecrosis and death from osteonecrosis 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.

8 Factors that must exist

At least one of the following factors must exist before it can be said that, on the balance of probabilities, osteonecrosis or death from osteonecrosis is connected with the circumstances of a person's relevant service:

- (1) experiencing blunt or penetrating trauma, including surgery, to the affected bone within the two years before the clinical onset of osteonecrosis;
- (2) having a fracture, dislocation of a joint or subluxation of a joint of the affected bone within the two years before the clinical onset of osteonecrosis;
- (3) smoking at least 20 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before the clinical onset of osteonecrosis, and where smoking has ceased, the clinical onset of osteonecrosis has occurred within five years of cessation;

Note: *pack-years of cigarettes, or the equivalent thereof in other tobacco products* is defined in the Schedule 1 - Dictionary.

- (4) consuming an average of at least 320 grams of alcohol per week, for at least six months within the one year before the clinical onset of osteonecrosis;

Note: Alcohol consumption is calculated utilising the Australian Standard of ten grams of alcohol per standard alcoholic drink.

- (5) having a solid organ malignancy at the time of the clinical onset of osteonecrosis;
- (6) having an autoimmune disorder from the specified list of autoimmune disorders at the time of the clinical onset of osteonecrosis;

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

- (7) having a haematological disease from the specified list of haematological diseases at the time of the clinical onset of osteonecrosis;
Note: *specified list of haematological diseases* is defined in the Schedule 1- Dictionary.
- (8) having a hypercoagulable state as specified at the time of the clinical onset of osteonecrosis;
Note: *hypercoagulable state as specified* is defined in the Schedule 1- Dictionary.
- (9) having chronic renal failure at least one year before the clinical onset of osteonecrosis;
Note: *chronic renal failure* is defined in the Schedule 1 – Dictionary.
- (10) having dyslipidaemia at the time of the clinical onset of osteonecrosis;
Note: *dyslipidaemia* is defined in the Schedule 1 – Dictionary.
- (11) having Cushing syndrome at the time of the clinical onset of osteonecrosis;
- (12) having infection with human immunodeficiency virus at the time of the clinical onset of osteonecrosis;
- (13) having a localised bacterial, viral or fungal infection at the affected site at the time of the clinical onset of osteonecrosis;
- (14) having osteomyelitis at the affected site at the time of the clinical onset of osteonecrosis;
- (15) having glucocorticoid therapy as specified, before the clinical onset of osteonecrosis, and where the glucocorticoid therapy as specified has ceased or decreased, the last dose of the therapy was received within the five years before the clinical onset of osteonecrosis;
Note: *glucocorticoid therapy as specified* is defined in the Schedule 1 - Dictionary.
- (16) taking bevacizumab, denosumab or testosterone within the 30 days before the clinical onset of osteonecrosis;
- (17) having a solid organ transplant, stem cell transplant or bone marrow transplant before the clinical onset of osteonecrosis;
- (18) undergoing a course of therapeutic radiation for cancer, where the affected site was in the field of radiation, before the clinical onset of osteonecrosis;
- (19) having internal deposition of radium-224, radium-226, or radium-228 before the clinical onset of osteonecrosis;
- (20) having decompression sickness within the two years before the clinical onset of osteonecrosis;

- (21) experiencing hyperbaric exposure as specified, within the two years before the clinical onset of osteonecrosis;

Note: *hyperbaric exposure as specified* is defined in the Schedule 1- Dictionary.

- (22) being pregnant at the time of the clinical onset of osteonecrosis;
- (23) undergoing childbirth within the one year before the clinical onset of osteonecrosis;
- (24) for osteonecrosis of the jaw only:
 - (a) having diabetes mellitus at the time of the clinical onset of osteonecrosis;
 - (b) having periodontitis, periodontal abscess or dental pulp and apical disease within the three months before the clinical onset of osteonecrosis;
 - (c) having syphilitic palatine gumma at the time of the clinical onset of osteonecrosis; or
 - (d) having acute herpes zoster involving the trigeminal nerve within the six months before the clinical onset of osteonecrosis;
 - (e) having substance use disorder, involving cocaine, at the time of the clinical onset of osteonecrosis;
 - (f) being treated with an osteoclast inhibitor for at least six months before the clinical onset of osteonecrosis, where the last dose of the drug was taken within the two years before the clinical onset of osteonecrosis; or

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

- (g) being treated with an antiangiogenic agent for at least six months before the clinical onset of osteonecrosis, where the last dose of the drug was taken within the two years before the clinical onset of osteonecrosis;

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

- (25) inability to obtain appropriate clinical management for osteonecrosis.

9 Relationship to service

- (1) The existence in a person of any factor referred to in section 8, must be related to the relevant service rendered by the person.
- (2) The factor set out in subsection 8(25) applies only to material contribution to, or aggravation of, osteonecrosis where the person's osteonecrosis was suffered or contracted before or during (but did not arise out of) the person's relevant service.

10 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 8 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 5

1 Definitions

In this instrument:

antiangiogenic agent means a drug that inhibits angiogenesis and is used in cancer therapy. Examples include, but are not limited to, bevacizumab, sunitinib and thalidomide.

chronic renal failure means:

- (a) having a glomerular filtration rate of less than 15 mL/min/1.73 m² for a period of at least three months; or
- (b) a need for renal replacement therapy (dialysis or transplantation) for treatment of complications of decreased glomerular filtration rate which would otherwise increase the risk of morbidity and mortality; or
- (c) undergoing chronic dialysis.

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

- (a) a total serum cholesterol level greater than 5.5 mmol/L; or
- (b) a serum low density lipoprotein level greater than 4.0 mmol/L; or
- (c) a serum high density lipoprotein cholesterol level less than 1.0 mmol/L.

equivalent glucocorticoid therapy means a glucocorticoid in the following table, at the doses specified in the table, or a therapeutically equivalent dose of another glucocorticoid:

Glucocorticoid	Minimum cumulative dose (milligrams)	Minimum average rate (milligrams/day)
betamethasone	475	1.3
cortisone	18 250	50
dexamethasone	585	1.6
hydrocortisone	14 600	40
methylprednisolone	2 920	8
paramethasone	1 460	4
prednisone	3 650	10
triamcinolone	2 920	8

glucocorticoid therapy as specified means:

- (a) taking prednisolone, orally or by injection:
 - (i) to a cumulative dose of at least 3 650 milligrams; and
 - (ii) at a minimum dose rate averaging 10 milligrams per day; or
- (b) taking equivalent glucocorticoid therapy, orally or by injection.

Note: **equivalent glucocorticoid therapy** is also defined in the Schedule 1 – Dictionary.

hyperbaric exposure as specified means an increase in the ambient barometric pressure exerted by the envelope of air or water surrounding the person, occurring with:

- (a) being in a pressurised tunnel or chamber for a continuous period of at least 30 minutes; or
- (b) being in a submerged craft or device, that is in a hyperbaric state, for a continuous period of at least 30 minutes; or
- (c) breath-hold diving to a depth of at least five metres and for a duration of at least one minute, on at least ten occasions within a continuous six month period; or
- (d) compression in a hyperbaric chamber; or
- (e) underwater diving with compressed air to a depth of at least 15 metres, for a continuous period of at least 30 minutes.

hypercoagulable state as specified means:

- (a) acquired activated protein C resistance;
- (b) acquired antithrombin III deficiency;
- (c) acquired dysfibrinogenaemia;
- (d) acquired protein C deficiency;
- (e) acquired protein S deficiency;
- (f) acquired thrombophilia;
- (g) antiphospholipid antibody syndrome;
- (h) disseminated intravascular coagulation;
- (i) haemolytic uraemic syndrome;
- (j) heparin-induced thrombocytopenia;
- (k) hyperfibrinogenaemia;
- (l) hyperproteinaemia;
- (m) hyperviscosity syndrome;
- (n) immune thrombocytopenia;
- (o) nephrotic syndrome;
- (p) paroxysmal nocturnal haemoglobinuria;
- (q) thrombocytosis; or
- (r) venom-induced thrombosis.

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

osteoclast inhibitor means a drug that inhibits mineralisation or resorption of the bone by blocking the action of osteoclasts, and includes, but is not limited to, bisphosphonates and denosumab.

Note: A single injection of an osteoclast inhibitor may be equivalent to a cumulative six month regimen of the drug.

osteonecrosis—see subsection 6(2).

pack-years of cigarettes, or the equivalent thereof in other tobacco products means a calculation of consumption where one pack-year of cigarettes equals twenty tailor-made cigarettes per day for a period of one calendar year, or 7 300 cigarettes. One tailor-made cigarette approximates one gram of tobacco or one gram of cigar or pipe tobacco by weight. One pack-year of tailor-made cigarettes equates to 7.3 kilograms of smoking tobacco by

weight. Tobacco products mean cigarettes, pipe tobacco or cigars, smoked alone or in any combination.

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 autoimmune disorders means:

- (a) antiphospholipid syndrome;
- (b) Behcet disease;
- (c) eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome);
- (d) giant cell arteritis;
- (e) granulomatosis with polyangiitis (Wegener granulomatosis);
- (f) Henoch-Schonlein purpura;
- (g) inflammatory bowel disease;
- (h) microscopic polyangiitis;
- (i) polyarteritis nodosa;
- (j) relapsing polychondritis;
- (k) rheumatoid arthritis;
- (l) sarcoidosis;
- (m) Sjogren syndrome;
- (n) systemic lupus erythematosus;
- (o) systemic sclerosis; or
- (p) Takayasu arteritis.

specified list of haematological diseases means:

- (a) haematological malignancy;
- (b) haemolytic anaemia;
- (c) haemophilia;
- (d) lymphoproliferative disease;
- (e) myeloproliferative disease;
- (f) sickle-cell disease; or
- (g) thalassaemia.

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*.