

Statement of Principles concerning OSTEOPOROSIS (Balance of Probabilities) (No. 67 of 2024)

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

Dated 20 August 2024.

Professor Terence Campbell AM Chairperson by and on behalf of The Repatriation Medical Authority

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1 Name

This is the Statement of Principles concerning *osteoporosis* (Balance of Probabilities) (No.67 of 2024).

2 Commencement

This instrument commences on 24 September 2024.

3 Authority

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

4 Repeal

The Statement of Principles concerning osteoporosis No. 99 of 2014 (Federal Register of Legislation No. F2014L01391) made under subsection 196B(3) of the VEA is repealed.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 osteoporosis and death from osteoporosis.

Meaning of osteoporosis

- (2) For the purposes of this Statement of Principles, osteoporosis:
 - (a) means a systemic bone disease characterised by low bone density resulting in a greater susceptibility to fracture (fragility fracture), where low bone mineral density is 2.5 standard deviations or more below the mean bone mineral density of young adult sex-matched controls (T score); or radiologically confirmed fragility fracture or loss of ≥20% of vertebral height due to fragility fractures; and the fragility fracture is not better explained by other types of bone pathology than osteoporosis; or anyone over 70 years with a low bone mineral density; or people with low bone density taking glucocorticoids for at least 3 months; and

- (b) excludes:
 - (i) localised osteoporosis;
 - (ii) Paget disease of bone;
 - (iii) osteomalacia;
 - (iv) osteonecrosis;
 - (v) osteomyelitis;
 - (vi) malignant or benign neoplasm of bone; and
 - (vii) osteogenesis imperfecta.

Note: low bone mineral density is defined in schedule 1 - Dictionary.

- (3) While osteoporosis attracts ICD-10-AM codes M80, M81 or M82, in applying this Statement of Principles the meaning of osteoporosis 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 osteoporosis

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

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

- (1) having rheumatoid arthritis or ankylosing spondylitis for at least the 2 years before clinical onset or clinical worsening;
- (2) having human immunodeficiency virus infection for at least the 2 years before clinical onset or clinical worsening;

- (3) having multiple sclerosis or Parkinson disease for at least the 2 years before clinical onset or clinical worsening;
- (4) having chronic renal impairment with a glomerular filtration rate of <30 ml/min/1.73 m2 for at least 3 months before clinical onset or clinical worsening;
- (5) having myeloma or systemic mastocytosis at the time of clinical onset or clinical worsening;
 - Note: *systemic mastocytosis* is defined in the Schedule 1 Dictionary.
- (6) having a solid organ (excluding corneal transplant), stem cell or bone marrow transplantation before clinical onset or clinical worsening;
- (7) having one of the following endocrine abnormalities for a continuous period of at least 2 years within the 5 years before clinical onset or clinical worsening;
 - (a) Cushing syndrome;
 - (b) Graves disease;
 - (c) hyperprolactinaemia;
 - (d) hyperthyroidism or thyrotoxicosis;
 - (e) hypogonadism (including menopause);
 - (f) primary hyperparathyroidism; or
 - (g) type 1 diabetes mellitus;
- (8) having one of the following gastrointestinal diseases at the time of clinical onset or clinical worsening;
 - (a) chronic exocrine pancreatic insufficiency;
 - (b) cirrhosis of the liver;
 - (c) coeliac disease; or
 - (d) inflammatory bowel disease.
- (9) having total or partial gastrectomy or a Roux-en-Y gastric bypass at least 1 year before clinical onset or clinical worsening;
- (10) for a minimal trauma fracture only, being pregnant within the 3 months before clinical onset;
- (11) having anorexia nervosa before clinical onset or clinical worsening; Note: *anorexia nervosa* is defined in the Schedule 1 – Dictionary.
- (12) taking one of the following glucocorticoids orally, intravenously or intramuscularly before clinical onset or worsening:
 - (a) betamethasone to a cumulative quantity of at least 60 mg within 6 months, or a cumulative quantity of at least 360 mg over any duration;

- (b) cortisone to a cumulative quantity of at least 2,500 mg within 6 months, or a cumulative quantity of at least 15,000 mg over any duration;
- (c) dexamethasone to a cumulative quantity of at least 75 mg within 6 months, or a cumulative quantity of at least 450 mg over any duration;
- (d) hydrocortisone to a cumulative quantity of at least 2,000 mg within 6 months, or a cumulative quantity of at least 12,000 mg over any duration;
- (e) methylprednisolone to a cumulative quantity of at least 400 mg within 6 months, or a cumulative quantity of at least 2,400 mg over any duration;
- (f) paramethasone to a cumulative quantity of at least 200 mg within 6 months, or a cumulative quantity of at least 1,200 mg over any duration;
- (g) prednisolone to a cumulative quantity of at least 500 mg within 6 months, or a cumulative quantity of at least 3,000 mg over any duration:
- (h) prednisone to a cumulative quantity of at least 500 mg within 6 months, or a cumulative quantity of at least 3,000 mg over any duration; or
- (i) a combination of glucocorticoids as weighted by dose equivalent to prednisolone, to a cumulative quantity of at least 500mg within 6 months, or a cumulative quantity at least 3,000 mg;

Note: *dose equivalence to prednisolone* is defined in the Schedule -1 – dictionary.

(13) taking a medication from the specified list before clinical onset or clinical worsening;

Note: taking a medication from the specified list is defined in the Schedule 1 – Dictionary.

(14) smoking at least 20 pack-years of cigarettes, or the equivalent thereof in other tobacco products, before clinical onset or clinical worsening, and where smoking has ceased, clinical onset or clinical worsening has occurred within 10 years of cessation;

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

(15) for males only, drinking at least 220 kilograms of alcohol within any 10 year period within the 20 years before clinical onset or clinical worsening;

Note: Alcohol consumption is calculated utilising the Australian Standard of 10 grams of alcohol per standard alcoholic drink.

(16) for females only, drinking at least 110 kilograms of alcohol within any 10 year period within the 20 years before clinical onset or clinical worsening;

Note: Alcohol consumption is calculated utilising the Australian Standard of 10 grams of alcohol per standard alcoholic drink.

- (17) having an altered dietary pattern resulting in a decrease in average daily calcium intake to 400 milligrams per day or less, for a period of at least 2 years before age 20 years, or for a period of at least 7 years after age 20 years, or the equivalent combination thereof, before clinical onset or clinical worsening;
- (18) consuming on average at least 7.5 milligrams per day of vitamin A over a period of at least 2 years within the 5 years before clinical onset or clinical worsening;
- (19) having severe vitamin C deficiency within the 5 years before clinical onset or clinical worsening;
 - Note: severe vitamin C deficiency is defined in the Schedule 1 Dictionary.
- (20) having vitamin D deficiency, with a serum 25(OH)D level of less than 50 nanomoles per litre, for a continuous period of at least 2 years within the 5 years before clinical onset or clinical worsening;
- (21) having haemochromatosis at the time of clinical onset or clinical worsening;
- (22) being exposed to cadmium at levels which have resulted in:
 - (a) renal damage; or
 - (b) a urinary cadmium level of at least 0.5 micrograms per gram creatinine for a period of at least 5 years,
 - before clinical onset or clinical worsening;
- (23) having gross diminution or near complete absence of movement of the body, such as would occur as a result of paralysis or strict bed rest for at least 6 months within the 2 years before clinical onset or clinical worsening;
- (24) an inability to undertake any physical activity greater than three METs for at least the 10 years before clinical onset or clinical worsening;

 Note: *MET* is defined in the Schedule 1 Dictionary.
- (25) having a BMI of less than 20 for a continuous period of at least 2 years within the 10 years before clinical onset or clinical worsening;

 Note: *BMI* is defined in the Schedule 1 Dictionary.
- (26) losing 10 % or more of body weight in any consecutive 2 year period when aged 50 years or older, within the 5 years before clinical onset or clinical worsening;
- (27) inability to obtain appropriate clinical management for osteoporosis before clinical worsening.

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 clinical worsening aspects of factors set out in section 9 apply only to material contribution to, or aggravation of, osteoporosis where the person's osteoporosis 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:

anorexia nervosa means a mental disorder that meets the following diagnostic criteria (derived from DSM-5-TR):

- (a) Restriction of energy intake relative to requirements, leading to a significantly low body weight in the context of age, sex, developmental trajectory, and physical health. Significantly low weight is defined as a weight that is less than minimally normal or, for children and adolescents, less than that minimally expected; and
- (b) Intense fear of gaining weight or of becoming fat, or persistent behaviour that interferes with weight gain, even though at a significantly low weight; and
- (c) Disturbance in the way in which one's body weight or shape is experienced, undue influence of body weight or shape on self-evaluation, or persistent lack of recognition of the seriousness of the current low body weight.

Note: **DSM-5-TR** is defined in the Schedule 1 – Dictionary.

BMI means body mass index and is calculated as follows:

 $BMI = W/H^2$ where:

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

DSM-5-TR means the American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision. Washington, DC, American Psychiatric Association, 2022.

dose equivalence to prednisolone means the quantity of the following drugs multiplied by the number in brackets to obtain an equivalent dose to prednisolone:

- (a) cortisone (x 5)
- (b) hydrocortisone.(x 4)
- (c) prednisone (x 1)1
- (d) methylprednisolone (x 0.8)
- (e) triamcinolone (x 0.8)
- (f) paramethasone (x 0.4)
- (g) dexamethasone (x 0.15)
- (h) betamethasone (x 0.12)

low bone mineral density is a bone mineral density 2.5 standard deviations or more below the mean bone mineral density of young adult sex-matched controls (T score).

MRCA means the Military Rehabilitation and Compensation Act 2004.

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, 1.0 kcal/kg of body weight per hour or resting metabolic rate.

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.

osteoporosis—see subsection 7(2).

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.

severe vitamin C deficiency means symptoms of scurvy or a serum ascorbic acid level of less than 2.5 milligrams per litre.

systemic mastocytosis means a mast cell hyperplasia that is generally detected in the bone marrow, skin, gastrointestinal mucosa, liver or spleen.

taking a medication from the specified list means taking any of the medications listed in the following table, according to route of administration, dosage and duration specified:

Medications	Mode	Dose	Minimum Duration of
			Treatment
corticotrophins	any route	at least weekly	6 months
gonadotrophin-	any route	any dose	6 months
releasing hormone			
analogues (GnRH)			
without treatment			
with agents that			
prevent bone loss			
cancer	any route	any dose	3 months
chemotherapy	excluding		
including	topical		
cyproterone			
methotrexate used	any route	any dose	3 months
for cancer treatment	excluding		
	topical		

Medications	Mode	Dose	Minimum
			Duration of
			Treatment
tamoxifen	oral	any dose	60 months
(premenopausal			
women only)			
aromatase inhibitors	oral	any dose	12 months
antiandrogen	any route	any dose	12 months
therapy (males only)			
medroxyprogesteron	oral or	any dose	12 months
e acetate, without	intramuscular		
any oestrogen			
supplementation			
(premenopausal			
women only)			
unfractionated	intravenous or	≥ 15,000	3 months
heparin	subcutaneous	units/day	
anticonvulsants	oral	any dose	24 months
lithium	oral	any dose	24 months
thiazolidinediones	oral	any dose	12 months

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.