

Statement of Principles

concerning

RESTLESS LEGS SYNDROME
(Reasonable Hypothesis)

(No. 113 of 2022)

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

Dated 21 October 2022.

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| The Common Seal of theRepatriation Medical Authoritywas affixed to this instrumentat the direction of: |
| Professor Terence Campbell AMChairperson |

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1. Name

This is the Statement of Principles concerning *restless legs syndrome* *(Reasonable Hypothesis)* (No. 113 of 2022).

1. Commencement

 This instrument commences on 21 November 2022.

1. Authority

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

1. Repeal

The Statement of Principles concerning restless legs syndrome No. 20 of 2014 (Federal Register of Legislation No. F2014L00307) made under subsections 196B(2) and (8) of the VEA is repealed.

1. 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.

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 restless legs syndrome and death from restless legs syndrome.

Meaning of **restless legs syndrome**

* 1. For the purposes of this Statement of Principles, restless legs syndrome:
		1. means a sensorimotor neurological disorder, in which there is:
			1. a strong urge to move the legs, usually accompanied or caused by uncomfortable and unpleasant sensations in the legs; and
			2. the urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and
			3. the urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching; and
			4. the urge to move or unpleasant sensations are worse in the evening or night than during the day, or only occur in the evening or night; and
		2. these clinical features:
			1. occur at least 3 times per week, and have persisted for at least 3 consecutive months; and
			2. cause significant distress, or impairment in behavioural, social, physical or occupational functioning; and
			3. are not solely accounted for by another medical or behavioural condition.

Note: Examples of other medical or behavioural conditions with clinical features that mimic restless legs syndrome include myalgia, venous stasis, leg oedema, arthritis, leg cramps and habitual foot tapping.

* 1. While restless legs syndrome attracts ICD‑10‑AM code G25.81, in applying this Statement of Principles the meaning of restless legs syndrome 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 **restless legs syndrome**

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

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

1. Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical‑scientific evidence that indicates that restless legs syndrome and death from restless legs syndrome 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.

1. 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 restless legs syndrome or death from restless legs syndrome with the circumstances of a person's relevant service:

* 1. having diabetes mellitus at the time of the clinical onset of restless legs syndrome;
	2. having iron deficiency at the time of the clinical onset of restless legs syndrome;

Note: ***iron deficiency*** is defined in the Schedule 1 – Dictionary.

* 1. having chronic renal failure at the time of the clinical onset of restless legs syndrome;

Note: ***chronic renal failure*** is defined in the Schedule 1 - Dictionary.

* 1. having a neurological disorder from the specified list of neurological disorders, involving the lower limbs, at the time of the clinical onset of restless legs syndrome;

Note: ***specified list of neurological disorders*** is defined in the Schedule 1 – Dictionary.

* 1. having Parkinson's disease at the time of the clinical onset of restless legs syndrome;
	2. taking a drug from the specified list of drugs:
		1. as prescribed for ongoing use; and
		2. within the 30 days before the clinical onset of restless legs syndrome;

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

* 1. having multiple sclerosis at the time of the clinical onset of restless legs syndrome;
	2. having a clinically significant disorder of mental health as specified at the time of the clinical onset of restless legs syndrome;

Note: ***clinically significant disorder of mental health as specified*** is defined in the Schedule 1 - Dictionary.

* 1. receiving spinal anaesthesia within the 30 days before the clinical onset of restless legs syndrome;
	2. having smoked tobacco products in an amount of at least 5 pack-years before the clinical onset of restless legs syndrome, and if smoking has ceased before the clinical onset of restless legs syndrome, then that onset occurred within 5 years of cessation;

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

* 1. being obese for at least the 5 years before the clinical onset of restless legs syndrome;

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

* 1. having narcolepsy or obstructive sleep apnoea at the time of the clinical onset of restless legs syndrome;
	2. being pregnant at the time of the clinical onset of restless legs syndrome;
	3. inability to undertake physical activity greater than 3 METs for a continuous period of at least the 1 year before the clinical onset of restless legs syndrome;

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

* 1. having dyslipidaemia for at least the 1 year before the clinical onset of restless legs syndrome;

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

* 1. having migraine at the time of the clinical onset of restless legs syndrome;
	2. having chronic obstructive pulmonary disease or asthma at the time of the clinical onset of restless legs syndrome;
	3. having a cerebrovascular accident within 3 months before the clinical onset of restless legs syndrome;
	4. having diabetes mellitus at the time of the clinical worsening of restless legs syndrome;
	5. having iron deficiency at the time of the clinical worsening of restless legs syndrome;

Note: ***iron deficiency*** is defined in the Schedule 1 – Dictionary.

* 1. having chronic renal failure at the time of the clinical worsening of restless legs syndrome;

Note: ***chronic renal failure*** is defined in the Schedule 1 - Dictionary.

* 1. having a neurological disorder from the specified list of neurological disorders, involving the lower limbs, at the time of the clinical worsening of restless legs syndrome;

Note: ***specified list of neurological disorders*** is defined in the Schedule 1 – Dictionary.

* 1. having Parkinson's disease at the time of the clinical worsening of restless legs syndrome;
	2. taking a drug from the specified list of drugs:
		1. as prescribed for ongoing use; and
		2. within the 30 days before the clinical worsening of restless legs syndrome;

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

* 1. having multiple sclerosis at the time of the clinical worsening of restless legs syndrome;
	2. having a clinically significant disorder of mental health as specified at the time of the clinical worsening of restless legs syndrome;

Note: ***clinically significant disorder of mental health as specified*** is defined in the Schedule 1 - Dictionary.

* 1. receiving spinal anaesthesia within the 30 days before the clinical worsening of restless legs syndrome;
	2. having smoked tobacco products in an amount of at least 5 pack-years before the clinical worsening of restless legs syndrome, and if smoking has ceased before the clinical worsening of restless legs syndrome, then that worsening occurred within 5 years of cessation;

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

* 1. being obese for at least the 5 years before the clinical worsening of restless legs syndrome;

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

* 1. having narcolepsy or obstructive sleep apnoea at the time of the clinical worsening of restless legs syndrome;
	2. being pregnant at the time of the clinical worsening of restless legs syndrome;
	3. inability to undertake physical activity greater than 3 METs for a continuous period of at least the 1 year before the clinical worsening of restless legs syndrome;

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

* 1. having dyslipidaemia for at least the 1 year before the clinical worsening of restless legs syndrome;

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

* 1. having migraine at the time of the clinical worsening of restless legs syndrome;
	2. having chronic obstructive pulmonary disease or asthma at the time of the clinical worsening of restless legs syndrome;
	3. having a cerebrovascular accident within the 3 months before the clinical worsening of restless legs syndrome;
	4. for restless legs syndrome augmentation only, taking a dopaminergic agent including levodopa and pramipexole, or tramadol, for a continuous period of at least the 3 months before that clinical worsening of restless legs syndrome;

Note: ***restless legs syndrome augmentation*** is defined in the Schedule 1 – Dictionary.

* 1. inability to obtain appropriate clinical management for restless legs syndrome.
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(19) to 9(38) apply only to material contribution to, or aggravation of, restless legs syndrome where the person's restless legs syndrome 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(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
	1. In this instrument:
		1. ***being obese*** means having a Body Mass Index (BMI) of 30 or greater.

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

* + 1. ***BMI*** means W/H2 where:
			1. W is the person's weight in kilograms; and
			2. H is the person's height in metres.
		2. ***chronic renal failure*** means:
			1. having a glomerular filtration rate of less than 15 mL/min/1.73 m2 for a period of at least 3 months; or
			2. 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
			3. undergoing chronic dialysis.
		3. ***clinically significant disorder of mental health as*** ***specified*** means one of the following conditions, which is of sufficient severity to warrant ongoing management:
			1. anxiety disorder;
			2. attention deficit hyperactivity disorder; or
			3. depressive disorder.

Note 1: Management of the condition may involve regular visits (for example, at least monthly) to a psychiatrist, counsellor or general practitioner.

Note 2: To warrant ongoing management does not require that any actual management was received or given for the condition.

* + 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 cholesterol 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. ***iron deficiency*** means having a serum ferritin level of less than 30 micrograms per litre.
		3. ***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.
		4. ***MRCA*** means the *Military Rehabilitation and Compensation Act 2004*.
		5. ***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. ***radiculopathy*** means a disease of the nerve roots resulting in symptoms of weakness, pain or loss of sensation.
		2. ***relevant service*** means:
			1. operational service under the VEA;
			2. peacekeeping service under the VEA;
			3. hazardous service under the VEA;
			4. British nuclear test defence service under the VEA;
			5. warlike service under the MRCA; or
			6. non-warlike service under the MRCA.

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

* + 1. ***restless legs syndrome***—see subsection 7(2).
		2. ***restless legs syndrome augmentation*** means a worsening of restless legs symptoms caused by long-term high dose drug therapy for that disease.

Note: Augmentation is characterised by more severe symptoms and earlier onset of symptoms during the day. It often involves the spread of symptoms to the arms or other regions of the body.

* + 1. ***specified list of drugs*** means:
			1. antipsychotics including olanzapine and quetiapine;
			2. enzalutamide;
			3. histamine H2-receptor antagonists including chlorpheniramine and hydroxyzine;
			4. lithium;
			5. proton pump inhibitors;
			6. selective serotonin re-uptake inhibitors including citalopram, escitalopram, fluoxetine and sertraline;
			7. serotonin-norepinephrine reuptake inhibitors including venlafaxine;
			8. tetracyclic antidepressants including mianserin and mirtazapine;
			9. topiramate;
			10. tricyclic antidepressants including amitriptyline; or
			11. zonisamide.
		2. ***specified list of neurological disorders*** means:
			1. a spinal cord lesion;
			2. peripheral neuropathy; or
			3. radiculopathy.

Note 1: Examples of causes of spinal cord lesions include transverse myelitis, neoplasm, trauma, syringomyelia and compression of the spine.

Note 2***: radiculopathy*** is 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*.