

Statement of Principles concerning MYASTHENIA GRAVIS (Balance of Probabilities) (No. 33 of 2024)

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

Dated 26 April 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 *myasthenia gravis (Balance of Probabilities)* (No. 33 of 2024).

2 Commencement

This instrument commences on 28 May 2024.

3 Authority

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

4 Repeal

The Statement of Principles concerning myasthenia gravis No. 76 of 2015 (Federal Register of Legislation No. F2015L00908) made under subsection 196B(3) of the VEA is repealed.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 myasthenia gravis and death from myasthenia gravis.

Meaning of myasthenia gravis

- (2) For the purposes of this Statement of Principles, myasthenia gravis:
 - (a) means an autoimmune neuromuscular disorder due to impaired neuromuscular signal transmission as a result of an immunologic process directed at acetylcholine receptors or other proteins of the postsynaptic membrane of the neuromuscular junction and characterised by weakness and fatigability of skeletal muscles; and
 - (b) excludes myasthenic syndromes such as congenital myasthenia gravis and Lambert-Eaton myasthenic syndrome.

Note: Examples of clinical worsening might include:

- (a) a persistent increase in the weakness of muscles already affected or when additional muscles are affected (such as the development of upper limb weakness when previously only ocular muscles were affected);
- (b) a persistent increase in the requirement for treatment of myasthenia gravis, which may include increasing the dose of a particular drug, the addition of new drugs, the introduction of plasma exchange or intravenous immunoglobulin, or the need for hospitalisation; and
- (c) an episode of severe myasthenia gravis resulting in myasthenic crisis or death.
- (3) While myasthenia gravis attracts ICD-10-AM code G70.0, in applying this Statement of Principles the meaning of myasthenia gravis 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 myasthenia gravis

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

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

- (1) being treated with one of the following medications within the 3 months before clinical onset:
 - (a) alemtuzumab:
 - (b) chloroquine;
 - (c) etanercept;
 - (d) gabapentin;
 - (e) HMG coenzyme A reductase inhibitors (statins);
 - (f) hydroxychloroquine;

- (g) immune checkpoint inhibitors including ipilimumab, nivolumab, pembrolizumab, atexolizumab, avelumab, dostarlimab, and durvalumab;
- (h) interferon alpha;
- (i) lithium carbonate;
- (j) penicillamine;
- (k) phenytoin;
- (1) trimethadione;
- (2) being treated with one of the following medications at the time of the clinical worsening:
 - (a) acetazolamide;
 - (b) alemtuzumab
 - (c) amantadine;
 - (d) amitriptyline;
 - (e) anaesthetic agents;
 - (f) antibiotics;
 - (g) beta-blockers;
 - (h) botulinum toxin;
 - (i) calcium channel blockers;
 - (j) carbamazepine;
 - (k) chloroquine;
 - (l) chlorpromazine;
 - (m) cocaine;
 - (n) colchicine;
 - (o) diphenhydramine;
 - (p) droperidol;
 - (q) echothiophate;
 - (r) ementine;
 - (s) ergometrine;
 - (t) etafenone;
 - (u) etanercept
 - (v) ethosuximide;
 - (w) gabapentin;
 - (x) haloperidol;
 - (y) HMG coenzyme A reductase inhibitors (statins);
 - (z) hydroxychloroquine;
 - (aa) imipramine;
 - (bb) immune checkpoint inhibitors;
 - (cc) interferon alpha;
 - (dd) interleukin-2;
 - (ee) levonorgestrel implant;
 - (ff) lithium carbonate;
 - (gg) magnesium sulphate;
 - (hh) mefloquine;
 - (ii) nicotine transdermal patch;
 - (jj) paraldehyde;

- (kk) potassium losing diuretics;
- (ll) penicillamine;
- (mm) peruvoside;
- (nn) phenytoin;
- (oo) procainamide;
- (pp) proguanil;
- (qq) propafenone;
- (rr) pyrantel pamoate;
- (ss) quinidine;
- (tt) quinine;
- (uu) ribavirin;
- (vv) sedative analgesics including barbiturates, muscle relaxants, narcotics and tranquillisers;
- (ww) systemic corticosteroids;
- (xx) thyroid hormone replacement therapy;
- (yy) tiopronin;
- (zz) trientine;
- (aaa) trihexyphenidyl;
- (bbb) trimethadione;
- (ccc) trimethaphan;
- (3) having an injection of an iodinated radiological contrast agent within the 24 hours before clinical worsening;

Note: Iodinated contrast agents include but are not limited to iothalamic acid, diatrizoate meglumine and diatrizoate sodium.

- (4) undergoing haematopoietic stem cell transplantation before clinical onset or clinical worsening;
- (5) being pregnant within the 6 weeks before clinical worsening;
- (6) having an infection with any of the following conditions in the 2 months before clinical worsening:
 - (a) pneumonia;
 - (b) influenza;
 - (c) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection;
 - (d) upper respiratory tract infection;
 - (e) urinary tract infection;
 - (f) gastrointestinal infection;
 - (g) septicaemia;
- (7) having major surgery or major trauma within the 2 months before clinical worsening;
- (8) receiving the ChAdOx1 nCoV-19 vaccine within the 2 months before clinical onset or clinical worsening;

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(9) experiencing a category 1A stressor within the 2 weeks before clinical worsening;

Note: *category 1A stressor* is defined in the Schedule 1 – Dictionary.

(10) experiencing a category 1B stressor within the 2 weeks before clinical worsening;

Note: *category 1B stressor* is defined in the Schedule 1 – Dictionary.

(11) experiencing a category 2 stressor within the 1 year before clinical onset;

Note 1: A category 2 stressor can arise in a variety of circumstances connected with service. Such circumstances can arise during the course of service, as a result of separation from service and the conditions associated with that separation, and in the transition to civilian life in the years following separation.

Note 2: category 2 stressor is defined in the Schedule 1 - Dictionary.

(12) having depressive disorder or anxiety disorder, sufficient to warrant ongoing management which may involve regular visits (for example, at least monthly) to a psychiatrist, counsellor or general practitioner, within the 6 months before clinical worsening;

Note: To warrant ongoing management does not require that any actual management was provided.

(13) inability to obtain appropriate clinical management for myasthenia gravis 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, myasthenia gravis where the person's myasthenia gravis 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:

category 1A stressor means one of the following severe traumatic events:

- (a) experiencing a life-threatening event;
- (b) being subject to a serious physical attack or assault including rape and sexual molestation; or
- (c) being threatened with a weapon, being held captive, being kidnapped, or being tortured.

category 1B stressor means one of the following severe traumatic events:

- (a) killing or maiming a person;
- (b) being a witness to a person being killed or critically injured;
- (c) being a witness to atrocities inflicted on another person;
- (d) participating in the clearance of a corpse or a critically injured casualty; or
- (e) viewing a corpse or a critically injured casualty as a witness.

Note: *corpse* and *witness* are defined in the Schedule 1 – Dictionary.

category 2 stressor means one of the following negative life events, the effects of which are chronic in nature and cause the person to feel on-going distress, concern or worry:

- (a) being socially isolated and unable to maintain friendships or family relationships, due to physical location, ethnicity, sexuality, disability, or medical or psychiatric illness;
- (b) experiencing a problem with a long-term relationship including the break-up of a close personal relationship, the need for marital or relationship counselling, marital separation, or divorce;
- (c) having concerns in the work or school environment including on-going disharmony with fellow work or school colleagues, perceived lack of social support within the work or school environment, perceived lack of control over tasks performed and stressful workloads, or experiencing bullying in the workplace or school environment;
- experiencing serious legal issues including being detained or held in custody, on-going involvement with the police concerning violations of the law, or court appearances associated with personal legal problems;
- (e) having severe financial hardship including loss of employment, long periods of unemployment, foreclosure on a property, or bankruptcy; or
- (f) having a family member or close friend experience a major deterioration in their health.

corpse means the human remains or body parts of one or more persons who have met a violent or horrific death.

Note: Examples of a violent or horrific death may include death due to suicide, gunshot, improvised explosive devices, natural and technological disasters, terrorist attacks or motor vehicle accidents. Seeing a closed body bag or viewing a body in an open-casket coffin are excluded from this definition.

MRCA means the *Military Rehabilitation and Compensation Act 2004*. *myasthenia gravis*—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.

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.

witness means a person who experiences an incident at the time it occurs and can give direct evidence of it. This excludes persons exposed only to public broadcasting or mass media coverage of the incident.