

Statement of Principles

concerning

MALIGNANT NEOPLASM OF THE ANUS AND ANAL CANAL
(Reasonable Hypothesis)

(No. 82 of 2022)

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

Dated 23 August 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 Definitions 7

1. Name

This is the Statement of Principles concerning *malignant neoplasm of the anus and anal canal* *(Reasonable Hypothesis)* (No. 82 of 2022).

1. Commencement

 This instrument commences on 19 September 2022.

1. Authority

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

1. Repeal

The Statement of Principles concerning malignant neoplasm of the anus and anal canal No. 51 of 2013 (Federal Register of Legislation No. F2013L01638) made under subsection 196B(2) of the VEA is repealed.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 malignant neoplasm of the anus and anal canal and death from malignant neoplasm of the anus and anal canal.

Meaning of **malignant neoplasm of the anus and anal canal**

* 1. For the purposes of this Statement of Principles, malignant neoplasm of the anus and anal canal:
		1. means a primary malignant neoplasm arising from the epithelial cells of the anus or anal canal; and
		2. includes:
			1. adenocarcinoma;
			2. adenocarcinoma in situ;
			3. carcinoma in situ;
			4. high-grade anal squamous intra-epithelial lesion (HSIL); and
			5. squamous cell carcinoma; and
		3. excludes:
			1. atypical squamous cell histology of undetermined significance in the anal canal;
			2. haematolymphoid tumours including Hodgkin's lymphoma and non-Hodgkin lymphoma;
			3. low-grade anal squamous intra-epithelial lesion (LSIL);
			4. malignant melanoma;
			5. mesenchymal tumours including soft tissue sarcoma;
			6. neoplasms of the perianal skin (anal margin); and
			7. neuroendocrine tumours.

Note: Anatomically, the anus and anal canal extends from the anus (anal verge) to the junction of the anal canal with the rectum, including the anorectal transformation zone.

* 1. While malignant neoplasm of the anus and anal canal attracts ICD‑10‑AM codes C21.0, C21.1, C21.2 or D01.3, in applying this Statement of Principles the meaning of malignant neoplasm of the anus and anal canal 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 **malignant neoplasm of the anus and anal canal**

* 1. For the purposes of this Statement of Principles, malignant neoplasm of the anus and anal canal,in relation to a person, includes death from a terminal event or condition that was contributed to by the person's malignant neoplasm of the anus and anal canal.

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 malignant neoplasm of the anus and anal canal and death from malignant neoplasm of the anus and anal canal 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 malignant neoplasm of the anus and anal canal or death from malignant neoplasm of the anus and anal canal with the circumstances of a person's relevant service:

* 1. having smoked tobacco products:
		1. in an amount of at least 10 pack-years before the clinical onset of malignant neoplasm of the anus or anal canal; and
		2. commencing at least 5 years before the clinical onset of malignant neoplasm of the anus or anal canal; and

if smoking has ceased before the clinical onset of malignant neoplasm of the anus or anal canal, then that onset occurred within 20 years of cessation;

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

* 1. having infection of the epithelium of the anal canal with a specified human papilloma virus before the clinical onset of malignant neoplasm of the anus or anal canal;

Note: ***specified human papillomavirus*** is defined in the Schedule 1 – Dictionary.

* 1. having receptive anal intercourse at least 2 years before the clinical onset of malignant neoplasm of the anus or anal canal;
	2. having infection with human immunodeficiency virus before the clinical onset of malignant neoplasm of the anus or anal canal;
	3. taking an immunosuppressive drug for organ or tissue transplantation for at least the 1 year before the clinical onset of malignant neoplasm of the anus or anal canal;

Note: ***organ or tissue transplantation*** is defined in the Schedule 1 - Dictionary.

* 1. having perianal manifestations of Crohn disease for at least the 3 years before the clinical onset of malignant neoplasm of the anus or anal canal;

Note: ***perianal manifestations of Crohn disease*** is defined in the Schedule 1 - Dictionary.

* 1. having systemic lupus erythematosus for at least 3 years before the clinical onset of malignant neoplasm of the anus or anal canal;
	2. having psoriasis for at least 3 years before the clinical onset of malignant neoplasm of the anus or anal canal;
	3. inability to obtain appropriate clinical management for malignant neoplasm of the anus and anal canal.
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 factor set out in subsection 9(9) applies only to material contribution to, or aggravation of, malignant neoplasm of the anus and anal canal where the person's malignant neoplasm of the anus and anal canal 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. ***malignant neoplasm of the anus and anal canal***—see subsection 7(2).
		2. ***MRCA*** means the *Military Rehabilitation and Compensation Act 2004*.
		3. ***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. ***organ or tissue transplantation*** means the transplantation of:

(a) all or part of an organ or tissue; or

(b) a substance obtained from an organ or tissue.

* + 1. ***perianal manifestations of Crohn disease*** means the presence of perianal fistula, perianal abscess, anal canal fissures or anal canal strictures associated with Crohn disease.
		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. ***specified human papillomavirus*** means human papilloma virus type 16, 18, 31, 33, 35, 45, 51, 52, 58 or 68.
		2. ***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.
		3. ***VEA*** means the *Veterans' Entitlements Act 1986*.