Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
GALLSTONE DISEASE (CHOLELITHIASIS) (Reasonable Hypothesis)
(No. 69 of 2025)

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

Dated 22 August 2025

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

Contents

1 Name 3

2 Commencement 3

3 Authority 3

4 Repeal 3

5 Application 3

6 Definitions 3

7 Kind of injury, disease or death to which this Statement of Principles relates 3

8 Basis for determining the factors 4

9 Factors that must exist 4

10 Relationship to service 7

11 Factors referring to an injury or disease covered by another Statement of Principles 7

Schedule 1 - Dictionary 8

1 Definitions 8

1 Name

This is the Statement of Principles concerning *gallstone disease (cholelithiasis) (Reasonable Hypothesis)* (No. 69 of 2025).

2 Commencement

This instrument commences on 22 September 2025.

3 Authority

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

4 Repeal

The Statement of Principles concerning cholelithiasis No. 51 of 2016 (Federal Register of Legislation No. F2016L00557) made under subsection 196B(2) of the VEA is repealed.

5 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.

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 gallstone disease (cholelithiasis) and death from gallstone disease (cholelithiasis).

*Meaning of **gallstone disease (cholelithiasis)***

(2) For the purposes of this Statement of Principles, gallstone disease (cholelithiasis) means the presence of one or more stones or calculi, exceeding 2 millimetres in diameter, in the gallbladder or intrahepatic or extrahepatic bile ducts, which result from the aggregation of bile constituents.

Note 1: Gallstones are typically composed of cholesterol, calcium salts of bilirubinate or palmitate, proteins and mucin.

Note 2: Gallstone disease (cholelithiasis) may present as biliary colic.

Note 3: Clinical worsening can include cholecystitis and cholangitis.

(3) While gallstone disease (cholelithiasis) attracts ICD-10-AM code K80, in applying this Statement of Principles the meaning of gallstone disease (cholelithiasis) 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 ***gallstone disease (cholelithiasis)***

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

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

8 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that gallstone disease (cholelithiasis) and death from gallstone disease (cholelithiasis) 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.

9 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 gallstone disease (cholelithiasis) or death from gallstone disease (cholelithiasis) with the circumstances of a person's relevant service:

(1) having a spinal cord injury at the time of clinical onset or clinical worsening;

Note: ***spinal cord injury*** is defined in the Schedule 1 - Dictionary.

(2) having a foreign body in the biliary tract, or a mechanical obstruction of the biliary tract, before clinical onset or clinical worsening;

Note: ***foreign body*** and ***mechanical obstruction of the biliary tract*** are defined in the Schedule 1 - Dictionary.

(3) having an ileal resection or ileal bypass within the 25 years before clinical onset or clinical worsening;

(4) having a gastric or oesophageal resection, or another operation that includes a vagotomy, within the 5 years before clinical onset or clinical worsening;

(5) having one of the following parasitic diseases of the biliary tract at the time of clinical onset or clinical worsening:

(a) ascariasis;
(b) clonorchiasis;
(c) dicrocoeliasis;
(d) fascioliasis;
(e) opisthorchiasis;
(f) trypanosomiasis;

(6) having bacterial infection of the biliary tract at the time of clinical onset or clinical worsening;

(7) having *Helicobacter pylori* infection of the biliary tract at the time of clinical onset or clinical worsening;

(8) having cholangiohepatitis or recurrent pyogenic cholangitis at the time of clinical onset or clinical worsening;

(9) having an acquired haemolytic disease, characterised by red cell defects and breakdown with bilirubin overproduction, within the 1 year before clinical onset or clinical worsening;

Note: Examples of an acquired haemolytic disease include autoimmune haemolytic anaemia caused by infections or medications, and haemolytic uraemic syndrome caused by bacterial infection.

(10) having worsening of an inherited haemolytic disease, characterised by red cell defects and breakdown with bilirubin overproduction, within the 1 year before clinical onset or clinical worsening;

Note: Examples of an inherited haemolytic disease include hereditary spherocytosis and sickle-cell disorder.

(11) having a somatostatinoma at the time of clinical onset or clinical worsening;

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

(12) being pregnant within the 6 months before clinical onset or clinical worsening;

(13) for males, being obese for at least the 2 years before clinical onset or clinical worsening;

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

(14) for females, being overweight or obese for at least the 2 years before clinical onset or clinical worsening;

Note: ***being overweight or obese*** is defined in the Schedule 1 - Dictionary.

(15) having rapid and extreme weight loss, involving a reduction of body mass by at least 15 percent:

(a) within a continuous 6 month period; or

(b) at an average rate of at least 1.5 kilograms per week, and

within the 2 years before clinical onset or clinical worsening;

Note: Situations which can be associated with rapid and extreme weight loss include bariatric surgery and the use of anti-obesity medications such as glucagon-like peptide 1 receptor agonists.

(16) having a very low-calorie diet, with an energy intake of less than 800 kilocalories per day, for the 6 months before clinical onset or clinical worsening;

(17) having type 2 diabetes mellitus at the time of clinical onset or clinical worsening;

Note: ***type 2 diabetes mellitus*** is defined in the Schedule 1 - Dictionary.

(18) having cirrhosis of the liver at the time of clinical onset or clinical worsening;

(19) having metabolic dysfunction-associated steatotic liver disease at the time of clinical onset or clinical worsening;

Note: Metabolic dysfunction-associated steatotic liver disease was previously known as non-alcoholic fatty liver disease.

(20) having hepatitis C virus infection at the time of clinical onset or clinical worsening;

(21) having Crohn disease or ulcerative colitis at the time of clinical onset or clinical worsening;

(22) taking any of the following medications for a continuous period of at least 3 months before clinical onset or clinical worsening, and where treatment has ceased, clinical onset or clinical worsening occurred within 3 months of cessation:

(a) atazanavir;
(b) cyclosporine A;
(c) fibrates;
(d) somatostatin analogues;
(e) tamoxifen;

(23) having oestrogen therapy for a continuous period of at least 3 months before clinical onset or clinical worsening, and where oestrogen therapy has ceased, clinical onset or clinical worsening occurred within 6 months of cessation;

Note: ***oestrogen therapy*** is defined in the Schedule 1 - Dictionary.

(24) having total parenteral nutrition for a continuous period of at least 3 weeks before clinical onset or clinical worsening, and where total parenteral nutrition has ceased, clinical onset or clinical worsening occurred within 30 days of cessation;

Note: ***total parenteral nutrition*** is defined in the Schedule 1 - Dictionary

(25) inability to undertake any physical activity greater than 3 METs for at least the 5 years before clinical onset or clinical worsening;

Note: MET (metabolic equivalent) is a unit of measure of the level of physical capability of the cardiorespiratory system. For example, 1 MET = cardiorespiratory effort associated with a person sitting, 3-4 METs = cardiorespiratory effort associated with a person walking at average walking pace (5 km/h) or light gardening.

(26) inability to obtain appropriate clinical management for gallstone disease (cholelithiasis) 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, gallstone disease (cholelithiasis) where the person's gallstone disease (cholelithiasis) 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(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

In this instrument:

being obese means:

(a) having a Body Mass Index (BMI) of 30 or greater; or
(b) for males, having a waist circumference exceeding 102 centimetres.

Note: Body mass index (BMI) is calculated as W/H^2 where:

(a) W is the person's weight in kilograms; and

(b) H is the person's height in metres.

being overweight or obese means:

(a) having a Body Mass Index (BMI) of 25 or greater; or
(b) for females, having a waist circumference exceeding 75 centimetres.

Note: Body mass index (BMI) is calculated as W/H^2 where:

(a) W is the person's weight in kilograms; and

(b) H is the person's height in metres.

foreign body means the presence of exogenous material, including a surgical clip or stent or nonabsorbable suture, a missile fragment or shrapnel, or a fish bone.

gallstone disease (cholelithiasis)—see subsection 7(2).

mechanical obstruction of the biliary tract means a structural or disease process, including benign or malignant stricture, sclerosing cholangitis, or choledochal cyst, which narrows the lumen of the biliary tract.

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

oestrogen therapy means the continuous, cyclical or intermittent administration of oestrogen contained in medications, including the oral contraceptive pill and menopausal hormone therapy.

relevant service means:

(a) operational service under the VEA;
(b) peacekeeping service under the VEA;
(c) hazardous service under the VEA;
(d) British nuclear test defence service under the VEA;
(e) warlike service under the MRCA; or
(f) non-warlike service under the MRCA.

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

somatostatinoma means a neuroendocrine neoplasm characterised by excessive secretion of somatostatin hormone by tumour cells of D-cell origin.

spinal cord injury means an injury to the long tracts of the spinal cord resulting in permanent motor or sensory deficits below the level of the lesion.

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.

total parenteral nutrition means continuous intravenous drip feeding with no feeding via mouth or gut.

type 2 diabetes mellitus means a form of diabetes mellitus caused by variable degrees of insulin resistance and impaired insulin secretion.

VEA means the *Veterans' Entitlements Act 1986*.