

# Statement of Principles concerning CIRRHOSIS OF THE LIVER (Reasonable Hypothesis) (No. 1 of 2017)

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

Dated 20 December 2016

The Common Seal of the Repatriation Medical Authority was affixed to this instrument at the direction of:

Professor Nicholas Saunders AO

Chairperson

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#### 1 Name

This is the Statement of Principles concerning *cirrhosis of the liver* (*Reasonable Hypothesis*) (No. 1 of 2017).

#### 2 Commencement

This instrument commences on 23 January 2017.

## 3 Authority

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

### 4 Revocation

The Statement of Principles concerning cirrhosis of the liver No. 107 of 2007, as amended, made under subsections 196B(2) and (8) of the VEA is revoked

## 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 cirrhosis of the liver and death from cirrhosis of the liver.

# Meaning of cirrhosis of the liver

- (2) For the purposes of this Statement of Principles, cirrhosis of the liver means a chronic condition of the hepatic parenchyma involving severe fibrosis in association with the formation of regenerative nodules.
- (3) While cirrhosis of the liver attracts ICD-10-AM code K70.3, K71.7 or K74.3-K74.6, in applying this Statement of Principles the meaning of cirrhosis of the liver 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),

Ninth Edition, effective date of 1 July 2015, copyrighted by the Independent Hospital Pricing Authority, ISBN 978-1-76007-020-5.

## Death from cirrhosis of the liver

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

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 cirrhosis of the liver and death from cirrhosis of the liver 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: *relevant service* is 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 cirrhosis of the liver or death from cirrhosis of the liver with the circumstances of a person's relevant service:

- (1) for males, consuming at least 110 kilograms of alcohol within any ten year period before the clinical onset of cirrhosis of the liver;
  - Note: *alcohol* is defined in the Schedule 1 Dictionary.
- (2) for females, consuming at least 55 kilograms of alcohol within any ten year period before the clinical onset of cirrhosis of the liver;
  - Note: alcohol is defined in the Schedule 1 Dictionary.
- (3) having received a cumulative equivalent dose of at least 0.4 sievert of ionising radiation to the liver before the clinical onset of cirrhosis of the liver;
  - Note: cumulative equivalent dose is defined in the Schedule 1 Dictionary.
- (4) having chronic infection with the hepatitis B virus before the clinical onset of cirrhosis of the liver;
  - Note: chronic infection with the hepatitis B virus is defined in the Schedule 1 Dictionary.
- (5) having chronic infection with the hepatitis C virus before the clinical onset of cirrhosis of the liver;
  - Note: *chronic infection with the hepatitis C virus* is defined in the Schedule 1 Dictionary.

- (6) having chronic infection with the hepatitis D virus before the clinical onset of cirrhosis of the liver;
  - Note: chronic infection with the hepatitis D virus is defined in the Schedule 1 Dictionary.
- (7) having infection with the hepatitis E virus before the clinical onset of cirrhosis of the liver;
  - Note: *infection with the hepatitis E virus* is defined in the Schedule 1 Dictionary.
- (8) having chronic hepatitis before the clinical onset of cirrhosis of the liver;
  - Note: *chronic hepatitis* is defined in the Schedule 1 Dictionary.
- (9) having autoimmune chronic active hepatitis before the clinical onset of cirrhosis of the liver;
  - Note: autoimmune chronic active hepatitis is defined in the Schedule 1 Dictionary.
- (10) having steatohepatitis before the clinical onset of cirrhosis of the liver;
- (11) being infected with human immunodeficiency virus, in the presence of chronic infection with the hepatitis B virus or chronic infection with the hepatitis C virus, before the clinical onset of cirrhosis of the liver;
  - Note: chronic infection with the hepatitis B virus and chronic infection with the hepatitis C virus are defined in the Schedule 1 Dictionary.
- (12) having evidence of chronic infection with schistosomiasis involving the liver before the clinical onset of cirrhosis of the liver;
- (13) having granulomatous liver disease before the clinical onset of cirrhosis of the liver;
  - Note: granulomatous liver disease is defined in the Schedule 1 Dictionary.
- (14) having severe right-sided cardiac failure for a continuous period of at least six months, within the five years before the clinical onset of cirrhosis of the liver;
  - Note: severe right-sided cardiac failure is defined in the Schedule 1 Dictionary.
- (15) having veno-occlusive disease for a continuous period of at least six months, within the five years before the clinical onset of cirrhosis of the liver;
  - Note: veno-occlusive disease is defined in the Schedule 1 Dictionary.
- (16) having a chronic partial or complete blockage to the passage of bile from the intrahepatic biliary system to the duodenum at the time of the clinical onset of cirrhosis of the liver;
- (17) having iron overload involving the liver at the time of the clinical onset of cirrhosis of the liver;
  - Note: *iron overload* is defined in the Schedule 1 Dictionary.

- (18) having alpha-1 antitrypsin deficiency before the clinical onset of cirrhosis of the liver;
- (19) having Gaucher's disease before the clinical onset of cirrhosis of the liver;
- (20) having Wilson's disease before the clinical onset of cirrhosis of the liver;
- (21) having Budd-Chiari syndrome for a continuous period of at least six months, within the five years before the clinical onset of cirrhosis of the liver:
  - Note: Budd-Chiari syndrome is defined in the Schedule 1 Dictionary.
- (22) consuming a daily average of at least 7.5 milligrams of vitamin A for a period of at least 18 months, or a cumulative dose of at least four grams, within the ten years before the clinical onset of cirrhosis of the liver;
- (23) being treated with methotrexate:
  - (a) for at least the six months; or
  - (b) to a cumulative dose of methotrexate of at least 500 milligrams taken over at least a three month period,
  - before the clinical onset of cirrhosis of the liver;
- (24) being treated with dideoxynucleoside-analogue drugs as specified for at least six months before the clinical onset of cirrhosis of the liver;
  - Note: *dideoxynucleoside-analogue drugs as specified* is defined in the Schedule 1 Dictionary.
- (25) inhaling or having cutaneous contact with carbon tetrachloride for a cumulative period of at least 500 hours within the five years before the clinical onset of cirrhosis of the liver;
- (26) inhaling a cumulative dose of at least 500 ppm-years of gaseous vinyl chloride before the clinical onset of cirrhosis of the liver;
  - Note: *ppm-years* is defined in the Schedule 1 Dictionary.
- (27) inhaling gaseous vinyl chloride for a cumulative period of at least 1 000 hours while working in the production or processing of vinyl chloride monomer or polyvinyl chloride before the clinical onset of cirrhosis of the liver;
- (28) for males, consuming at least 110 kilograms of alcohol within any ten year period before the clinical worsening of cirrhosis of the liver;
  - Note: *alcohol* is defined in the Schedule 1 Dictionary.
- (29) for females, consuming at least 55 kilograms of alcohol within any ten year period before the clinical worsening of cirrhosis of the liver;
  - Note: alcohol is defined in the Schedule 1 Dictionary.

- (30) having received a cumulative equivalent dose of at least 0.4 sievert of ionising radiation to the liver before the clinical worsening of cirrhosis of the liver;
  - Note: cumulative equivalent dose is defined in the Schedule 1 Dictionary.
- (31) having chronic infection with the hepatitis B virus before the clinical worsening of cirrhosis of the liver;
  - Note: chronic infection with the hepatitis B virus is defined in the Schedule 1 Dictionary.
- (32) having chronic infection with the hepatitis C virus before the clinical worsening of cirrhosis of the liver;
  - Note: chronic infection with the hepatitis C virus is defined in the Schedule 1 Dictionary.
- (33) having chronic infection with the hepatitis D virus before the clinical worsening of cirrhosis of the liver;
  - Note: chronic infection with the hepatitis D virus is defined in the Schedule 1 Dictionary.
- (34) having infection with the hepatitis E virus before the clinical worsening of cirrhosis of the liver;
  - Note: infection with the hepatitis E virus is defined in the Schedule 1 Dictionary.
- (35) having chronic hepatitis before the clinical worsening of cirrhosis of the liver;
  - Note: chronic hepatitis is defined in the Schedule 1 Dictionary.
- (36) having autoimmune chronic active hepatitis before the clinical worsening of cirrhosis of the liver;
  - Note: autoimmune chronic active hepatitis is defined in the Schedule 1 Dictionary.
- (37) having steatohepatitis before the clinical worsening of cirrhosis of the liver:
- (38) being infected with human immunodeficiency virus, in the presence of chronic infection with the hepatitis B virus or chronic infection with the hepatitis C virus, before the clinical worsening of cirrhosis of the liver;
  - Note: *chronic infection with the hepatitis B virus* and *chronic infection with the hepatitis C virus* are defined in the Schedule 1 Dictionary.
- (39) having evidence of chronic infection with schistosomiasis involving the liver before the clinical worsening of cirrhosis of the liver;
- (40) having granulomatous liver disease before the clinical worsening of cirrhosis of the liver;
  - Note: granulomatous liver disease is defined in the Schedule 1 Dictionary.

(41) having severe right-sided cardiac failure for a continuous period of at least six months, within the five years before the clinical worsening of cirrhosis of the liver;

Note: severe right-sided cardiac failure is defined in the Schedule 1 - Dictionary.

(42) having veno-occlusive disease for a continuous period of at least six months, within the five years before the clinical worsening of cirrhosis of the liver:

Note: veno-occlusive disease is defined in the Schedule 1 - Dictionary.

- (43) having a chronic partial or complete blockage to the passage of bile from the intrahepatic biliary system to the duodenum at the time of the clinical worsening of cirrhosis of the liver;
- (44) having iron overload involving the liver at the time of the clinical worsening of cirrhosis of the liver;

Note: iron overload is defined in the Schedule 1 - Dictionary.

- (45) having alpha-1 antitrypsin deficiency before the clinical worsening of cirrhosis of the liver;
- (46) having Gaucher's disease before the clinical worsening of cirrhosis of the liver;
- (47) having Wilson's disease before the clinical worsening of cirrhosis of the liver;
- (48) having Budd-Chiari syndrome for a continuous period of at least six months, within the five years before the clinical worsening of cirrhosis of the liver;

Note: **Budd-Chiari syndrome** is defined in the Schedule 1 - Dictionary.

- (49) consuming a daily average of at least 7.5 milligrams of vitamin A for a period of at least 18 months, or a cumulative dose of at least four grams, within the ten years before the clinical worsening of cirrhosis of the liver;
- (50) being treated with methotrexate:
  - (a) for at least the six months; or
  - (b) to a cumulative dose of methotrexate of at least 500 milligrams taken over at least a three month period,

before the clinical worsening of cirrhosis of the liver;

(51) being treated with dideoxynucleoside-analogue drugs as specified for at least six months before the clinical worsening of cirrhosis of the liver;

Note: *dideoxynucleoside-analogue drugs as specified* is defined in the Schedule 1 - Dictionary.

- (52) inhaling or having cutaneous contact with carbon tetrachloride for a cumulative period of at least 500 hours within the five years before the clinical worsening of cirrhosis of the liver;
- (53) inhaling a cumulative dose of at least 500 ppm-years of gaseous vinyl chloride before the clinical worsening of cirrhosis of the liver;
  - Note: *ppm-years* is defined in the Schedule 1 Dictionary.
- (54) inhaling gaseous vinyl chloride for a cumulative period of at least 1 000 hours while working in the production or processing of vinyl chloride monomer or polyvinyl chloride before the clinical worsening of cirrhosis of the liver;
- (55) inability to obtain appropriate clinical management for cirrhosis of the liver

## 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 factors set out in subsections 9(28) to 9(55) apply only to material contribution to, or aggravation of, cirrhosis of the liver where the person's cirrhosis of the liver 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:

*alcohol* is measured by the alcohol consumption calculations utilising the Australian Standard of ten grams of alcohol per standard alcoholic drink.

autoimmune chronic active hepatitis means a chronic disorder of autoimmunity characterised by continuing hepatocellular necrosis and inflammation and seroimmunologic abnormalities.

**Budd-Chiari syndrome** means symptomatic obstruction or occlusion of the hepatic veins or hepatic portion of the inferior vena cava, characterised by hepatomegaly, abdominal pain and tenderness, ascites, mild jaundice, and eventually, portal hypertension and liver failure.

*chronic hepatitis* means symptomatic, biochemical or infectious agent biomarker evidence of continuing or relapsing hepatocellular necrosis and hepatic inflammation for at least six months.

*chronic infection with the hepatitis B virus* means infection with the hepatitis B virus resulting in a chronic infection of at least six months duration and which must be confirmed by laboratory testing for hepatitis B serological or nucleic acid markers, or both.

*chronic infection with the hepatitis C virus* means infection with the hepatitis C virus resulting in a chronic infection of at least six months duration and which must be confirmed by laboratory testing for hepatitis C serological or nucleic acid markers, or both.

*chronic infection with the hepatitis D virus* means infection with the hepatitis D virus resulting in a chronic infection of at least six months duration and which must be confirmed by laboratory testing for hepatitis D serological or nucleic acid markers, or both.

*cirrhosis of the liver*—see subsection 7(2).

cumulative equivalent dose means the total dose of ionising radiation received by the particular organ or tissue. The formula used to calculate the cumulative equivalent dose allows doses from multiple types of ionising radiation to be combined, by accounting for their differing biological effect. The unit of equivalent dose is the sievert. For the purposes of this Statement of Principles, the calculation of cumulative equivalent dose excludes doses received from normal background radiation, but includes therapeutic radiation, diagnostic radiation, cosmic radiation at high altitude, radiation from occupation-related sources and radiation from nuclear explosions or accidents.

*dideoxynucleoside-analogue drugs as specified* means didanosine, stavudine or zalcitabine.

*granulomatous liver disease* means an inflammatory liver disease characterised by granuloma formation in the liver and associated with many disorders such as sarcoidosis, infections (tuberculosis, brucellosis, syphilis), and adverse drug reactions.

*infection with the hepatitis E virus* means infection with the hepatitis E virus resulting in an infection of at least six months duration and which must be confirmed by laboratory testing for hepatitis E serological or nucleic acid markers, or both.

*iron overload* means an accumulation of excess iron in tissues and organs which has been confirmed by elevated ferritin or transferrin saturation levels. Causes include haemochromatosis and blood transfusions.

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

*ppm-years* means parts per million multiplied by years of exposure.

### 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 also defined in the Schedule 1 - Dictionary.

*severe right-sided cardiac failure* means a reduced ability of the right ventricle to process venous return, evidenced by marked venous and liver congestion and extensive peripheral oedema.

*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.

*veno-occlusive disease* means symptomatic occlusion of the sublobular branches of the hepatic veins or the small hepatic venules.