



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
BRONCHIOLITIS OBLITERANS
ORGANISING PNEUMONIA
(Reasonable Hypothesis)
(No. 79 of 2018)

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

Dated 24 August 2018

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

A handwritten signature in black ink, appearing to read 'N. Saunders'.

Professor Nicholas Saunders AO
Chairperson

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1 Name

This is the Statement of Principles concerning *bronchiolitis obliterans organising pneumonia (Reasonable Hypothesis)* (No. 79 of 2018).

2 Commencement

This instrument commences on 24 September 2018.

3 Authority

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

4 Repeal

The Statement of Principles concerning bronchiolitis obliterans organising pneumonia No. 62 of 2009 (Federal Register of Legislation No. F2009L03225) made under subsection 196B(2) of the VEA is repealed.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 bronchiolitis obliterans organising pneumonia and death from bronchiolitis obliterans organising pneumonia.

*Meaning of **bronchiolitis obliterans organising pneumonia***

- (2) For the purposes of this Statement of Principles, bronchiolitis obliterans organising pneumonia:
- (a) means a histological pattern of organising pneumonia consisting of the patchy filling of alveoli, alveolar ducts and bronchioles by loose plugs of granulation tissue consisting of fibroblasts embedded in connective tissue, arising in response to lung injury and resulting in excessive proliferation of healing tissue, with:
- (i) respiratory symptoms; or
- (ii) other clinical evidence of pulmonary dysfunction; and

- (b) excludes:
- (i) organising pneumonia secondary to infectious pneumonia or acute respiratory distress syndrome;
 - (ii) organising pneumonia that occurs in the presence of another interstitial lung disease and is not the dominant histological finding;
 - (iii) organising pneumonia that occurs as a pulmonary manifestation of a systemic disease; and
 - (iv) pulmonary inflammation that is confined to the bronchioles (obliterative bronchiolitis, proliferative bronchiolitis).

Note 1: Bronchiolitis obliterans organising pneumonia ('BOOP') is also known as cryptogenic organising pneumonia.

Note 2: Although the definition refers to a histological pattern, the diagnosis of bronchiolitis obliterans organising pneumonia can be made in patients with typical clinical and radiographic features without a lung biopsy being undertaken.

Death from bronchiolitis obliterans organising pneumonia

- (3) For the purposes of this Statement of Principles, bronchiolitis obliterans organising pneumonia, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's bronchiolitis obliterans organising pneumonia.

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 bronchiolitis obliterans organising pneumonia and death from bronchiolitis obliterans organising pneumonia 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 bronchiolitis obliterans organising pneumonia or death from bronchiolitis obliterans organising pneumonia with the circumstances of a person's relevant service:

- (1) taking a drug or a drug from a class of drugs from the specified list of drugs, at the time of the clinical onset of bronchiolitis obliterans organising pneumonia;

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

- (2) being treated with a drug which is associated in the individual with the following:
 - (a) the development of bronchiolitis obliterans organising pneumonia within six months of commencing drug therapy; and
 - (b) the absence of bronchiolitis obliterans organising pneumonia prior to commencing drug therapy; and
 - (c) clinical improvement within weeks of ceasing drug therapy; and
 - (d) exclusion of other aetiologies for bronchiolitis obliterans organising pneumonia;
- (3) having a solid organ transplant, stem cell transplant or bone marrow transplant before the clinical onset of bronchiolitis obliterans organising pneumonia;
- (4) undergoing a course of therapeutic radiation for the treatment of malignant neoplasm of the breast or malignant neoplasm of the lung within the two years before the clinical onset of bronchiolitis obliterans organising pneumonia;
- (5) having bronchial obstruction immediately adjacent to a focus of pulmonary organisation, at the time of the clinical onset of bronchiolitis obliterans organising pneumonia;

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

- (6) inhaling high concentrations of a substance with irritant properties, where:
 - (a) the inhalation has resulted in signs and symptoms of acute damage to the lower respiratory tract within the 48 hours after the inhalation; and
 - (b) the clinical onset of bronchiolitis obliterans organising pneumonia occurs within the 30 days following the inhalation of the substance;
- (7) inhaling sulphur mustard (mustard gas) resulting in signs and symptoms of acute damage to the lower respiratory tract within the 30 days before the clinical onset of bronchiolitis obliterans organising pneumonia;
- (8) having gastro-oesophageal reflux disease at the time of the clinical onset of bronchiolitis obliterans organising pneumonia;
- (9) taking a drug or a drug from a class of drugs from the specified list of drugs, at the time of the clinical worsening of bronchiolitis obliterans organising pneumonia;

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

- (10) being treated with a drug which is associated in the individual with the following:
 - (a) the worsening of bronchiolitis obliterans organising pneumonia within six months of commencing drug therapy; and
 - (b) clinical improvement within weeks of ceasing drug therapy;
- (11) having a solid organ transplant, stem cell transplant or bone marrow transplant before the clinical worsening of bronchiolitis obliterans organising pneumonia;
- (12) undergoing a course of therapeutic radiation for the treatment of malignant neoplasm of the breast or malignant neoplasm of the lung within the two years before the clinical worsening of bronchiolitis obliterans organising pneumonia;
- (13) having bronchial obstruction immediately adjacent to a focus of pulmonary organisation, at the time of the clinical worsening of bronchiolitis obliterans organising pneumonia;

Note: *bronchial obstruction* is defined in the Schedule 1 - Dictionary.
- (14) inhaling high concentrations of a substance with irritant properties, where:
 - (a) the inhalation has resulted in signs and symptoms of acute damage to the lower respiratory tract within the 48 hours after the inhalation; and
 - (b) the clinical worsening of bronchiolitis obliterans organising pneumonia occurs within the 30 days following the inhalation of the substance;
- (15) inhaling sulphur mustard (mustard gas) resulting in signs and symptoms of acute damage to the lower respiratory tract within the 30 days before the clinical worsening of bronchiolitis obliterans organising pneumonia;
- (16) having gastro-oesophageal reflux disease at the time of the clinical worsening of bronchiolitis obliterans organising pneumonia;
- (17) inability to obtain appropriate clinical management for bronchiolitis obliterans organising pneumonia.

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(9) to 9(17) apply only to material contribution to, or aggravation of, bronchiolitis obliterans organising pneumonia where the person's bronchiolitis obliterans organising

pneumonia 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:

bronchial obstruction means occlusion of the lumen of a bronchus or bronchiole due to an endogenous pathological process or structure, or from exogenous material, such as a foreign body.

bronchiolitis obliterans organising pneumonia—see subsection 7(2).

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

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.

specified list of drugs means:

- (a) amiodarone;
- (b) amphotericin B;
- (c) azathioprine;
- (d) beta-blockers;
- (e) bleomycin;
- (f) bucillamine;
- (g) busulphan;
- (h) carbamazepine;
- (i) cephalosporins;
- (j) chlorambucil;
- (k) cocaine;
- (l) cyclophosphamide;
- (m) cytosine arabinoside;
- (n) daptomycin;
- (o) dihydroergocryptine;
- (p) doxorubicin;
- (q) dronedarone;
- (r) everolimus;
- (s) fluvastatin;
- (t) gemcitabine;
- (u) gold salts (aurothiopropanosulfonate);
- (v) interferons alpha, beta and gamma;
- (w) ipilimumab;
- (x) irinotecan;

- (y) lamotrigine;
- (z) lenalidomide;
- (aa) L-tryptophan;
- (bb) mecamlamine;
- (cc) mesalamine;
- (dd) methotrexate;
- (ee) minocycline;
- (ff) mitomycin-c;
- (gg) nilutamide;
- (hh) nitrofurantoin;
- (ii) oxaliplatin;
- (jj) penicillamine;
- (kk) phenytoin;
- (ll) propylthiouracil;
- (mm) quinine (intravenous);
- (nn) risedronate;
- (oo) rituximab;
- (pp) simvastatin (simvastin);
- (qq) sirolimus;
- (rr) sulfasalazine;
- (ss) tacrolimus;
- (tt) temozolomide;
- (uu) temsirolimus;
- (vv) thalidomide;
- (ww) ticlopidine; or
- (xx) trastuzumab.

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*.