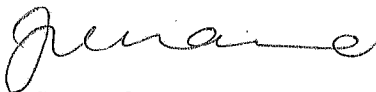


SPECIAL ARRANGEMENT FOR OPIATE DEPENDENCE TREATMENT PROGRAM

I, Julianne Quaine, Assistant Secretary, Pharmaceutical Access Branch, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this special arrangement under subsection 100 (1) of the *National Health Act 1953*.

Dated 6 April 2016



Julianne Quaine

Assistant Secretary
Pharmaceutical Access Branch
Pharmaceutical Benefits Division
Department of Health

1 Purpose

The purpose of this special arrangement is to provide for the supply of certain pharmaceutical benefits for the purpose of treating opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal.

2 Commencement

This special arrangement is to commence on 1 January 2016.

3 Revocation

This special arrangement revokes the special arrangement titled 'Special Arrangement for Opiate Dependence Treatment Program' that was made on 30 June 2014.

4 Pharmaceutical benefits available under this special arrangement

- (1) The pharmaceutical benefits that are available under this special arrangement are listed in Schedule 1. In this special arrangement, these pharmaceutical benefits are referred to as 'opiate treatment drugs'.
- (2) The term 'pharmaceutical benefit' has the meaning given in subsection 84(1) of the *National Health Act 1953* (the Act).

5 Authorised prescriber

- (1) Only an authorised prescriber may write a prescription for the supply of an opiate treatment drug. Medical practitioners and authorised nurse practitioners are authorised prescribers of opiate treatment drugs (see subsection 88(1) of the Act and the instrument made under section 88 of the Act).
- (2) The term 'medical practitioner' has the meaning given in subsection 3(1) of the *Health Insurance Act 1973* and the term 'authorised nurse practitioner' has the meaning given in subsection 84(1) of the Act.

5 Prescription circumstances

- (1) Determinations made under subsection 85(7) and section 85A of the Act in relation to:
 - (a) the circumstances in which a prescription for the supply of an opiate treatment drug may be written;
 - (b) the maximum quantity or number of units of the pharmaceutical item in an opiate treatment drug that may be directed to be supplied on any one occasion; and
 - (c) the maximum number of occasions on which the supply of an opiate treatment drug may, in one prescription, be directed to be repeated,do not apply to an opiate treatment drug prescribed under this special arrangement.
- (2) The only circumstance in which a prescription for the supply of an opiate treatment drug may be written under this special arrangement is for the treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal.

6 Entitlement to receive opiate treatment drugs

- (1) Subject to this special arrangement, a patient is entitled to receive an opiate treatment drug if the patient:
 - (a) is, or is to be treated as, an eligible person within the meaning of the *Health Insurance Act 1973*; and
 - (b) is receiving medical treatment by a medical practitioner or is receiving nurse practitioner treatment by an authorised nurse practitioner.
- (2) The term 'nurse practitioner treatment' has the meaning given in subsection 84(1) of the Act.

7 Supply of opiate treatment drugs to patients

Under this special arrangement, an opiate treatment drug may only be supplied to a patient by an authorised State or Territory supplier. An 'authorised State or Territory supplier' means a person permitted, by the relevant State or Territory, to supply an opiate treatment drug to a patient in that State or Territory.

8 Charges for the supply of opiate treatment drugs

- (1) Subject to section 9, a responsible person who supplies an opiate treatment drug to an authorised State or Territory supplier under this special arrangement must not demand or receive any payment or other valuable consideration in respect of the supply.
- (2) Subject to subsection (3), an authorised State or Territory supplier who supplies an opiate treatment drug to a patient under this special arrangement must not demand or receive any payment or other valuable consideration in respect of the supply.
- (3) An authorised State or Territory supplier may charge the patient an administration fee if such a fee is permitted by the relevant State or Territory Department or authority that regulates the supply of opiate treatment drugs.

9 Commonwealth payments

- (1) A responsible person who has supplied an opiate treatment drug to an authorised State or Territory supplier under this special arrangement is entitled to be paid by the Commonwealth the price ex-manufacturer for each pack supplied. The 'responsible person' for each opiate treatment drug available under this special arrangement is specified in Schedule 1.
- (2) A responsible person must submit a claim for payment to the Department of Health monthly.
- (3) The claim for payment must be in writing and must:
 - (a) specify the name and address of each authorised State or Territory supplier to whom opiate treatment drugs were supplied in the month;
 - (b) specify the number of packs of each opiate treatment drug supplied to each authorised State or Territory supplier in the month;
 - (c) specify the number of packs of each opiate treatment drug supplied in each State and Territory in the month and the amount claimed for the supply of each opiate treatment drug in each State and Territory in the month;
 - (d) specify the number of packs of all opiate treatment drugs supplied in each State and Territory in the month and the amount claimed for the supply of all opiate treatment drugs in each State and Territory in the month;

- (e) specify the total number of packs of each opiate treatment drug supplied in Australia in the month and the amount claimed for the supply of each opiate treatment drug in Australia in the month; and
- (f) specify the total number of packs of all opiate treatment drugs supplied in Australia in the month and the amount claimed for the supply of all opiate treatment drugs in Australia in the month.

10 State and Territory law

A person who prescribes or supplies an opiate treatment drug for the purposes of this special arrangement must, at all times, act in accordance with State and Territory law.

11 Application of the Act and instruments made for the purposes of Part VII of the Act

A provision of Part VII of the Act, or of regulations or other instruments made for Part VII of the Act, applies subject to this special arrangement.

THIS DOCUMENT HAS BEEN RELEASED UNDER
THE FREEDOM OF INFORMATION ACT 1982
BY THE DEPARTMENT OF HEALTH AND AGED CARE

Schedule 1 - Pharmaceutical benefits covered by this special arrangement							
Listed Drug	Form	Manner of Administration	Brand	Responsible Person	Authorised Prescriber	Circumstances	Section 100 only ¹
Buprenorphine	Tablet (sublingual) 400 micrograms (as hydrochloride)	Sublingual	Subutex	Indivior Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	PB
	Tablet (sublingual) 2 mg (as hydrochloride)	Sublingual	Subutex	Indivior Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	PB
	Tablet (sublingual) 8 mg (as hydrochloride)	Sublingual	Subutex	Indivior Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	PB
Buprenorphine with naloxone	Film (soluble) 2 mg (as hydrochloride)- 0.5 mg (as hydrochloride)	Sublingual	Suboxone Film 2/0.5	Indivior Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	D
	Film (soluble) 8 mg (as hydrochloride)- 2 mg (as hydrochloride)	Sublingual	Suboxone Film 8/2	Indivior Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	D

Methadone	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 200 mL	Oral	Biodone Forte	Biomed Aust Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	PB
			Aspen Methadone Syrup	Aspen Pharma Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	*
	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 1 L	Oral	Biodone Forte	Biomed Aust Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	PB
			Aspen Methadone Syrup	Aspen Pharma Pty Ltd	Medical practitioner Authorised nurse practitioner	Treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal	PB

1 In this column the letter 'D' means that the listed drug can only be supplied in accordance with this special arrangement or another special arrangement relating to the listed drug and the letter 'PB' means that the pharmaceutical benefit can only be supplied in accordance with this special arrangement or another special arrangement relating to the pharmaceutical benefit.

* This pharmaceutical benefit can only be prescribed for the treatment of opiate dependence, including for detoxification (withdrawal) and maintenance of withdrawal under this special arrangement. It can be prescribed in other circumstances under the general operation of Part VII of the Act.