

PB 18 of 2012

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2012 (No. 2)

National Health Act 1953

I, FELICITY McNEILL, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing, delegate of the Minister for Health, make this instrument under subsections 100(1) and (2) of the *National Health Act 1953*.

Dated 27 March 2012

FELICITY McNEILL

First Assistant Secretary Pharmaceutical Benefits Division Department of Health and Ageing

1 Name of Instrument

- (1) This Instrument is the National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2012 (No. 2).
- (2) This Instrument may also be cited as PB 18 of 2012.

2 Commencement

This Instrument commences on 1 April 2012.

3 Amendments to PB 79 of 2011

Schedule 1 amends the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011).

Schedule 1 Amendments

[1] Definitions, after distribution fee

omit definition of dose and substitute:

dose, for a chemotherapy drug, means the quantity of the drug contained in an infusion, including unit of use, such as international units, grams, micrograms, or milligrams.

[2] Definitions, after supplier

insert:

under co-payment data means information in relation to the supply under this Special Arrangement of:

- (a) an infusion by an approved pharmacist, approved medical practitioner, approved hospital authority, or HSD hospital authority; or
- (b) a related pharmaceutical benefit by a participating hospital authority; where a claim is not payable as the dispensed price for the supply under this Special Arrangement does not exceed the amount that the supplier was entitled to charge under subsection 54(2) or 55(2) for supply of an infusion, or under subsection 57(2) for supply of a related pharmaceutical benefit.

Note: The definition of under co-payment data does not apply to a non-approved hospital authority.

[3] After section 35

omit:

Part 4 Claims and payment

Division 1 Claims for payment

and substitute

Part 4 Claims, payment and provision of under co-payment data

Division 1 Claims for payment and provision of under co-payment data

[4] After subsection 36(2)

omit section 37 and substitute

37 Modified references for claim and provision of under co-payment data

- (1) The rules made by the Minister under subsection 99AAA(8) and subsection 98AC(4) of the Act apply to a claim or provision of under co-payment data as follows:
 - (a) a reference to an approved supplier or an approved hospital authority includes a reference to an HSD hospital authority;
 - (b) a reference to a number allotted to an approval under regulation 8A of the Regulations includes a reference to a number allotted to an approval under section 52 of the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010* for a HSD hospital authority; and
 - (c) the definition of under co-payment data in section 4 of this Special Arrangement replaces the definition of under co-payment data appearing in the rules made under subsection 98AC(4) of the Act.

[5] After section 38

omit section 39 and substitute:

39 Modified requirements for supply of infusion

For a claim or provision of under co-payment data for supply of an infusion, the requirements in the rules made by the Minister under subsection 99AAA(8) and subsection 98AC(4) of the Act are modified as follows:

- (a) a reference to a pharmaceutical benefit includes a reference to an infusion;
- (b) a reference to an authority prescription in the rules includes a reference to an authority prescription within the meaning given by section 3 of this Special Arrangement;
- (c) the claim or provision of under co-payment data must include:
 - (i) a drug code for each chemotherapy drug in the infusion, being the code for the drug published in the *Schedule of Pharmaceutical Benefits* published by the Department; and
 - (ii) the dose of each chemotherapy drug in the infusion; and
 - (iii) for a claim submitted on or after 1 April 2012 the authority prescription number or Streamlined Authority Code in relation to each circumstance, if any, for which authorisation of the prescription or medication chart is required;
- (d) the supplier is not required to include in the claim or provision of under co-payment data:
 - (i) the PBS/RPBS Item Code for the supplied pharmaceutical benefit;
 - (ii) the brand of the supplied pharmaceutical item;
 - (iii) whether or not regulation 24 applies; or
 - (iv) whether or not immediate supply was necessary.

Note: Section 34 of this Special Arrangement provides that regulation 24, subregulations 25(2) to (4), and subsection 84AAA(1) (early supply) do not apply to the supply of an infusion under this Special Arrangement.

[6]	Schedule 1	l Part 1. entre	y for Bleomycin
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substitute:

Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U.	Injection	Bleo 15K	WQ	MP	C1139 C1198	D
			Hospira Pty Limited	HH	MP	C1139 C1198	D

[7] Schedule 1 Part 1, entry for Bortezomib

Insert in the column headed 'Section 100 only':

D

[8] Schedule 1 Part 1, entry for Doxorubicin in the form Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 10 mg in 5 mL single dose vial with manner of administration Injection/intravesical and brand Adriamycin Solution

substitute:

Doxorubicin	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 10 mg in 5 mL single dose vial	Injection/ intravesical	Accord Doxorubicin	WQ	MP	D
			Adriamycin Solution	PF	MP	D

[9] Schedule 1 Part 1, entry for Doxorubicin in the form Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial with manner of administration Injection/intravesical and brand Adriamycin

substitute:

Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial	Injection/ intravesical	Accord Doxorubicin	WQ	MP	D
		Adriamycin	PF	MP	D

[10] Schedule 1 Part 1, entry for Epirubicin in the form Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL with manner of administration Injection/intravesical and brand Epirubicin Actavis 10

substitute:

Epirubicin	Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL	Injection/ intravesical	Epiccord	WQ	MP	D
			Epirubicin Actavis 10	TA	MP	D

substitute:		T	1=.	1,,,,	T.,	
	Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL	Injection/ intravesical	Epiccord	WQ	MP	
	mg in 10 mz	milavooloai	Epirubicin Actavis 20	TA	MP	
manner of ad	art 1, after entry for Epirubicin in the form Solution for ir ministration Injection/intravesical and brand DBL Epirubumns in the order indicated:			oride 200	mg in 10	0 mL with
			Epiccord	WQ	MP	
			Epirubicin Kabi	PK	MP	
			T =	1	T T	
			Epirubicin Kabi	PK	MP	
administratio	art 1, entry for Epirubicin in the form Solution for injection Injection/intravesical and brand Epirubicin Actavis 50	on containing e		•		
		on containing e		•		
administratio		Injection/		•		
administratio	n Injection/intravesical and brand Epirubicin Actavis 50 Solution for injection containing epirubicin hydrochloride 50	Injection/	pirubicin hydrochloride	50 mg in	25 mL wi	th manne
administration substitute: 15] Schedule 1 Particular of administration	n Injection/intravesical and brand Epirubicin Actavis 50 Solution for injection containing epirubicin hydrochloride 50	Injection/ intravesical	pirubicin hydrochloride Epiccord Epirubicin Actavis 50	50 mg in	25 mL wi	th manne
administration substitute: 15] Schedule 1 Part of administration	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL art 1, after entry for Epirubicin in the form Solution for intion Injection/intravesical and brand Epirubicin Ebewe	Injection/ intravesical	pirubicin hydrochloride Epiccord Epirubicin Actavis 50	50 mg in	25 mL wi	th manne
administration substitute: 15] Schedule 1 Particular of administration insert in the columns and the substitute:	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL art 1, after entry for Epirubicin in the form Solution for intion Injection/intravesical and brand Epirubicin Ebewe tumns in the order indicated: art 1, after entry for Methotrexate in the form Injection 50	Injection/ intravesical njection contain	Epirubicin hydrochloride Epirubicin Actavis 50 Ling epirubicin hydrochloride Epirubicin Kabi	50 mg in WQ TA Dride 50	MP MP MP MP	th manne
administration substitute: 15] Schedule 1 Paragraph of administration insert in the column of the c	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL art 1, after entry for Epirubicin in the form Solution for intion Injection/intravesical and brand Epirubicin Ebewe tumns in the order indicated: art 1, after entry for Methotrexate in the form Injection 50	Injection/ intravesical njection contain	Epirubicin hydrochloride Epirubicin Actavis 50 Ling epirubicin hydrochloride Epirubicin Kabi	50 mg in WQ TA Dride 50	MP MP MP MP	th manne

[17] Schedule 1 Part 1, after entry for Methotrexate in the form Solution concentrate for I.V. infusion 1000 mg in 10 mL vial with manner of administration Injection and brand Hospira Pty Limited

insert in the columns in the order indicated:

	Methaccord	WQ	MP	PB

[18] Schedule 5, entry for Bleomycin, in the column headed 'Approved Ex-manufacturer Price'

omit:

\$40.89

substitute:

\$34.35

[19] Schedule 5, entry for Bleomycin, in the column headed 'Claimed Ex-manufacturer Price'

omit:

\$77.67

substitute:

\$65.24

Note

All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See http://www.frli.gov.au.

Instrument Number PB 18 of 2012