

SUMMARY OF CHANGES

The explanatory notes section of this schedule provides information on the prescribing and dispensing of chemotherapy drugs under the Efficient Funding of Chemotherapy Drugs — Section 100 Arrangements.

In addition to the commencement of these new arrangements, the changes listed below take effect from 1 January 2012.

Additions

Additions – Forms

7246J, 4439P	Gemcitabine	Injection	Solution for injection 200 mg (as hydrochloride) in 5.3 mL (<i>DBL Gemcitabine Injection, HH</i>)
7246J, 4439P	Gemcitabine	Injection	Solution for injection 1 g (as hydrochloride) in 26.3 mL (<i>DBL Gemcitabine Injection, HH</i>)
7246J, 4439P	Gemcitabine	Injection	Solution for injection 2 g (as hydrochloride) in 52.6 mL (<i>DBL Gemcitabine Injection, HH</i>)

Additions – Brands

7222D, 4309T	Carboplatin	Injection	<i>Carboplatin Kabi, PK</i> (Solution for I.V. injection 450 mg in 45 mL)
7249M, 4451G	Irinotecan Hydrochloride Trihydrate	Injection	<i>Tecan, WQ</i> (I.V. injection 500 mg in 25 mL)
7254T, 4567J	Paclitaxel	Injection	<i>Paclitaxel Pfizer, PF</i> (Solution concentrate for I.V. infusion 30 mg in 5 mL)
7254T, 4567J	Paclitaxel	Injection	<i>Paclitaxel Pfizer, PF</i> (Solution concentrate for I.V. infusion 100 mg in 16.7 mL)
7254T, 4567J	Paclitaxel	Injection	<i>Paclitaxel Pfizer, PF</i> (Solution concentrate for I.V. infusion 300 mg in 50 mL)

Addition – Caution

The following caution has been added to all **Gemcitabine** items:

CAUTION

Pharmaceutical benefits containing gemcitabine may have different concentrations.

EFFICIENT FUNDING OF CHEMOTHERAPY – SECTION 100 ARRANGEMENTS

Explanatory Notes

In addition to the drugs and medicinal preparations listed in the Schedule of Pharmaceutical Benefits, a number of drugs are also available as pharmaceutical benefits but are distributed under alternative arrangements. These alternative arrangements are provided for under section 100 of the *National Health Act 1953*.

Section 100 cancer chemotherapy drugs

New prescribing and dispensing arrangements for certain chemotherapy drugs subsidised by the Pharmaceutical Benefits Scheme (PBS) will take effect from 1 December 2011 under the Revised Arrangements for the Efficient Funding of Chemotherapy Drugs initiative (Revised Arrangements).

Chemotherapy drugs used for the treatment of cancer and administered through infusion or injection are covered by these Revised Arrangements. From 1 December 2011 the Revised Arrangements will operate under a new section 100 program which will include certain intravenous chemotherapy drugs, as listed in this Schedule, which were previously supplied through:

- the General Pharmaceutical Benefits Schedule (section 2)
- the Special Authority Program (trastuzumab - Herceptin®), and
- the current Chemotherapy Pharmaceutical Access Program (CPAP).

The Revised Arrangements will apply for both public hospitals and private hospitals/clinics. While private hospitals/clinics will move to the Revised Arrangements from 1 December 2011, the implementation in public hospitals will be phased in until 31 March 2012.

- Where public hospitals have moved to the Revised Arrangements, they will need to comply with the new guidelines for writing prescriptions as set out below.
- Where public hospitals have NOT moved to the Revised Arrangements they can continue to use the existing CPAP S100 arrangements, for supply within the hospital, that currently apply for chemotherapy infusibles (please refer to the CPAP schedule for details).
- Where public hospital prescribers write prescriptions for chemotherapy infusibles, that are to be dispensed outside public hospitals, they will need to comply with the new guidelines for writing prescriptions as set out below.

This Schedule is split into two parts:

Chemotherapy items for public hospital use

Chemotherapy items for private hospital/private clinic use

Prescribing and Supplying - Information for PBS Prescribers and Pharmacists

Drugs are listed based on the relevant unit of measure. Prescribers of chemotherapy drugs must write dose specific prescriptions, which specify the amount of active ingredient/s required for a single infusion or injection using milligrams or other relevant units of measure.

- Prescribing will exclude reference to forms and strengths
- Loading and maintenance doses will need to be prescribed separately
- Prescriptions will no longer take the form of an order for a certain number of items, but will instead order an amount of a drug or drugs at the generic (drug) level
- Prescribers retain the right to prescribe by brand.

This Schedule has been updated to include:

- one item code per drug (in most circumstances) under which brands, forms and strengths are listed
- maximum amount (which replaces maximum quantity) refers to the upper limit in milligrams or other relevant unit of measure

Dispensing software has been upgraded to include an algorithm which will calculate the most cost-efficient combination of vial sizes that make up the required patient dose (one prescription) and calculate the level of remuneration paid.

The algorithm does not determine how the infusion is prepared, however remuneration will be made based on the most cost-efficient combination of vial sizes. Pharmacists will still be able to dispense any subsidised brand or combination of brands.

A dose variation will be allowed by up to 10 percent from the original amount prescribed without requirement for a new prescription on the recommendation of the prescriber.

THERAPEUTIC INDEX

CHEMOTHERAPY ITEMS FOR PRIVATE HOSPITAL/PRIVATE CLINIC USE.....	9
<i>Antineoplastic and immunomodulating agents.....</i>	11
Antineoplastic agents	11
Alkylating agents.....	11
Antimetabolites	11
Plant alkaloids and other natural products.....	14
Cytotoxic antibiotics and related substances	20
Other antineoplastic agents	21
CHEMOTHERAPY ITEMS FOR PUBLIC HOSPITAL USE	37
<i>Antineoplastic and immunomodulating agents.....</i>	39
Antineoplastic agents	39
Alkylating agents.....	39
Antimetabolites	39
Plant alkaloids and other natural products.....	42
Cytotoxic antibiotics and related substances	48
Other antineoplastic agents	49

Special Pharmaceutical Benefits for Private Hospital/Private Clinic use

The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients. Other than for bleomycin sulfate, exemptions on medical grounds are available. For eligible veterans under RPBS provisions, see RPBS EXPLANATORY NOTES, paragraph 28, in the Schedule of Pharmaceutical Benefits.

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Proposed Dispensed Price for Max. Amount	Total Dispensed Price for Max. Amount	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer
------	--	----------------	----------------	---------------	---	--	--	--

Antineoplastic and immunomodulating agents

Antineoplastic agents

Cytotoxic antibiotics and related substances

Other cytotoxic antibiotics

BLEOMYCIN SULFATE

Restricted Benefit

Germ cell neoplasms.

Restricted Benefit

Lymphoma.

7244G	Injection	30000 i.u.	11	\$80.92	165.13	246.05	35.40	Hospira Pty Limited (Powder for injection 15,000 i.u.)	HH
-------	-----------	------------	----	---------	--------	--------	-------	--	----

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer
					Price for Max. Amount \$	Recordable Value for Safety Net \$	

PEMETREXED DISODIUM

Authority Required

Locally advanced or metastatic non-small cell lung cancer, after prior platinum-based chemotherapy.

Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval.

Authority Required

Mesothelioma in combination with cisplatin.

Doses greater than 500 mg per metre squared body surface area (BSA) will not be approved for PBS subsidy. The patient's BSA must be provided at the time of the authority approval.

Note

No applications for increased maximum quantities for the 500 mg vial will be authorised.

7255W	Injection	1100 mg	5	-	3559.88	35.40	Alimta (Powder for I.V. infusion 100 mg (base))	LY
							Alimta (Powder for I.V. infusion 500 mg (base))	LY

RALTITREXED

Authority Required (STREAMLINED)

3185

For use as a single agent in the treatment of advanced colorectal cancer.

7256X	Injection	7 mg	8	-	1129.05	35.40	Tomudex (Powder for I.V. infusion 2 mg)	HH
-------	-----------	------	---	---	---------	-------	---	----

Purine analogues

CLADRIBINE

Authority Required (STREAMLINED)

3180

Hairy cell leukaemia.

7225G	Injection	17 mg	6	-	1407.33	35.40	Leustatin (Solution for I.V. infusion 10 mg in 10 mL) Litak (Injection 10 mg in 5 mL)	JC OA
-------	-----------	-------	---	---	---------	-------	--	----------

FLUDARABINE PHOSPHATE

Authority Required (STREAMLINED)

3887

B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.

Stage A progressive disease is defined by at least one of the following: persistent rise in lymphocyte count with doubling time less than 12 months; a downward trend in haemoglobin or platelets, or both; more than 50% increase in the size of liver, spleen, or lymph nodes, or appearance of these signs if not previously present; constitutional symptoms attributable to disease.

The diagnosis of chronic lymphocytic leukaemia (CLL) must have been established based on:

- (a) a lymphocytosis, with more than 5000 million lymphocytes per L in the peripheral blood; and
- (b) a clonal population of B-cells (CD5/CD19) documented by flow cytometry.

Note

Pharmaceutical benefits that have the form fludarabine phosphate powder for I.V. injection 50 mg (after reconstitution) and pharmaceutical benefits that have the form fludarabine phosphate solution for I.V. injection 50 mg are equivalent for the purposes of substitution.

7233Q	Injection	55 mg	29	-	645.59	35.40	^a Farine (Powder for I.V. injection 50 mg)	WQ
							^a Fludara (Powder for I.V. injection 50 mg)	GZ
							^a Fludarabine Actavis (Powder for I.V. injection 50 mg)	TA
							^a Fludarabine Ebewe (Solution for I.V. injection 50 mg in 2 mL)	SZ

Pyrimidine analogues

CYTARABINE

7227J	Injection	7000 mg	15	-	809.47	35.40	Pfizer Australia Pty Ltd (Injection 100 mg in 5 mL)	PF
-------	-----------	---------	----	---	--------	-------	---	----

FLUOROURACIL

Restricted Benefit

For patients requiring administration of fluorouracil by intravenous infusion.

7234R	Injection	5500 mg	11	-	117.33	35.40	Fluorouracil Ebewe (Injection 5000 mg in 100 mL)	SZ
							^a DBL Fluorouracil Injection BP (Injection 1000 mg in 20 mL)	HH

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
							^a Gemcitabine Actavis (Powder for I.V. infusion 200 mg (as hydrochloride))	TA
							^a Gemcitabine Ebewe (Powder for I.V. infusion 1 g (as hydrochloride))	SZ
							^a Gemcitabine Ebewe (Powder for I.V. infusion 200 mg (as hydrochloride))	SZ
							^a Gemcitabine Ebewe (Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL)	SZ
							^a Gemcitabine Ebewe (Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL)	SZ
							^a Gemcitabine Kabi (Powder for I.V. infusion 1 g (as hydrochloride))	PK
							^a Gemcitabine Kabi (Powder for I.V. infusion 200 mg (as hydrochloride))	PK
							^a Gemcitabine Kabi (Powder for I.V. infusion 2 g (as hydrochloride))	PK
							^a Gemcitabine Sun (Powder for I.V. infusion 1 g (as hydrochloride))	ZF
							^a Gemcitabine Sun (Powder for I.V. infusion 200 mg (as hydrochloride))	ZF
							^a Gemcite (Powder for I.V. infusion 1 g (as hydrochloride))	ZP
							^a Gemcite (Powder for I.V. infusion 200 mg (as hydrochloride))	ZP
							^a Gemplan (Powder for I.V. infusion 1 g (as hydrochloride))	WQ
							^a Gemplan (Powder for I.V. infusion 200 mg (as hydrochloride))	WQ
							^a Gemzar (Powder for I.V. infusion 1 g (as hydrochloride))	LY
							^a Gemzar (Powder for I.V. infusion 200 mg (as hydrochloride))	LY

Plant alkaloids and other natural products

Vinca alkaloids and analogues

VINBLASTINE SULFATE								
7261E	Injection	20 mg	17	-	135.93	35.40	Hospira Pty Limited (Solution for I.V. injection 10 mg in 10 mL)	HH
VINCRIStINE SULFATE								
7262F	Injection	2 mg	7	-	103.53	35.40	^a Hospira Pty Limited (I.V. injection 1 mg in 1 mL) ^a Pfizer Australia Pty Ltd (I.V. injection 1 mg in 1 mL)	HH PF

VINORELBINE

Authority Required (STREAMLINED)

3890

Locally advanced or metastatic non-small cell lung cancer.

Authority Required (STREAMLINED)

3907

Advanced breast cancer after failure of prior therapy which includes an anthracycline.

7263G	Injection	70 mg	7	-	475.57	35.40	^a Hospira Pty Limited (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	HH
							^a Hospira Pty Limited (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	HH
							^a Navelbine (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	FB
							^a Navelbine (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	FB
							^a Vinorelbine Ebewe (Solution for I.V. infusion 10 mg (as tartrate) in 1 mL)	SZ
							^a Vinorelbine Ebewe (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	SZ
							^a Vinorelbine Kabi (Solution for I.V. infusion 50 mg (as tartrate) in 5 mL)	PK

Podophyllotoxin derivatives

ETOPOSIDE								
7237X	Injection	440 mg	14	-	221.27	35.40	Etopophos (Powder for I.V. infusion 100 mg (as phosphate)) Etopophos (Powder for I.V. infusion 1 g (as phosphate))	BQ BQ

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed	Maximum	Brand, Form, Strength and Manufacturer
					Price for Max. Amount \$	Recordable Value for Safety Net \$	
DOCETAXEL							
Caution							
Pharmaceutical benefits containing docetaxel may have different concentrations.							
Authority Required (STREAMLINED)							
3956							
Treatment of HER2 positive breast cancer in combination with trastuzumab.							
Note							
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.							
Note							
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.							
7282G	Injection	250 mg	5	-	3883.76	35.40	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL) HH Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL) TA ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL) HH ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL) HH ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL) SZ ^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL) SZ ^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL) TA ^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL) TA ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent) SW ^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent) SW ^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL) SW ^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL) SW
DOCETAXEL							
Caution							
Pharmaceutical benefits containing docetaxel may have different concentrations.							
Authority Required (STREAMLINED)							
3888							
Neoadjuvant treatment of a patient with a WHO performance status of 1 or less, with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx, in combination with cisplatin and fluorouracil.							
Note							
The carcinoma can be considered inoperable for technical or organ preservation reasons.							
Note							
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL, docetaxel solution concentrate for I.V. infusion 20 mg in 2 mL and docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.							
Note							
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL, docetaxel solution concentrate for I.V. infusion 80 mg in 8 mL and docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.							
7283H	Injection	250 mg	5	-	3883.76	35.40	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL) HH Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL) TA ^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL) HH

Chemotherapy Items for Private Hospital/Private Clinic use

Code	Name, Restriction, Manner of Administration	Max. Amount	No. of Rpts	Premium \$	Dispensed Price for Max. Amount \$	Maximum Recordable Value for Safety Net \$	Brand, Form, Strength and Manufacturer	
DOCETAXEL								
Caution								
Pharmaceutical benefits containing docetaxel may have different concentrations.								
Authority Required (STREAMLINED)								
3890								
Locally advanced or metastatic non-small cell lung cancer.								
Authority Required (STREAMLINED)								
3186								
Advanced metastatic ovarian cancer after failure of prior therapy which includes a platinum compound.								
Authority Required (STREAMLINED)								
3884								
Treatment of androgen independent (hormone refractory) metastatic carcinoma of the prostate in a patient with a Karnofsky performance-status score of at least 60%. Docetaxel must be used as first-line chemotherapy and administered in three weekly cycles.								
Note								
A maximum of 10 cycles of treatment with docetaxel will be authorised under this restriction.								
Authority Required (STREAMLINED)								
3955								
Metastatic breast cancer.								
Note								
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 20 mg in 1 mL and 20 mg in 2 mL, docetaxel concentrate for I.V. infusion 20 mg (after reconstitution) and docetaxel powder for I.V. infusion 20 mg (after reconstitution) are equivalent for the purposes of substitution.								
Note								
Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 80 mg in 4 mL and 80 mg in 8 mL, docetaxel concentrate for I.V. infusion 80 mg (after reconstitution) and docetaxel powder for I.V. infusion 80 mg (after reconstitution) are equivalent for the purposes of substitution.								
7285K	Injection	250 mg	5	-	3883.76	35.40	DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 160 mg in 16 mL)	HH
							Oncotaxel 140 (Solution concentrate for I.V. infusion 140 mg in 7 mL)	TA
							^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 20 mg in 2 mL)	HH
							^a DBL Docetaxel Concentrated Injection (Solution concentrate for I.V. infusion 80 mg in 8 mL)	HH
							^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 20 mg in 2 mL)	HX
							^a Docetaxel Ebewe (Solution concentrate for I.V. infusion 80 mg in 8 mL)	HX
							^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 20 mg in 2 mL)	SZ
							^a Docetaxel Sandoz (Solution concentrate for I.V. infusion 80 mg in 8 mL)	SZ
							^a Docetaxel SUN (Powder for I.V. infusion 20 mg with solvent)	ZF
							^a Docetaxel SUN (Powder for I.V. infusion 80 mg with solvent)	ZF
							^a Oncotaxel 20 (Solution concentrate for I.V. infusion 20 mg in 1 mL)	TA
							^a Oncotaxel 80 (Solution concentrate for I.V. infusion 80 mg in 4 mL)	TA
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent)	SW
							^a Taxotere (Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 20 mg in 1 mL)	SW
							^a Taxotere (Solution concentrate for I.V. infusion 80 mg in 4 mL)	SW

