PB 77 of 2012

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2012 (No. 8)

National Health Act 1953

I, KIM BESSELL, First Assistant Secretary A/g, 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 25 September 2012

KIM BESSELL
First Assistant Secretary A/g
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. 8).*

(2) This Instrument may also be cited as PB 77 of 2012.

2 Commencement

This Instrument commences on 1 October 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] Schedule 1 Part 1, after entry for Bortezomib in the form Powder for injection 3.5mg with manner of administration Injection and brand Velcade

insert in the columns in the order indicated:

	Powder for Injection 1mg	Injection	Velcade	JC	MP	C7003 C7004 C7005 C7006 C7007	D

[2] Schedule 1 Part 1, entry for Etoposide in the form Solution for I.V. infusion 100 mg in 5 mL vial with manner of administration Injection

omit:

			Hospira Pty Limited	HH	MP		PB

[3] Schedule 1 Part 1, entry for Gemcitabine in the form Powder for I.V. infusion 1g (as hydrochloride) with manner of administration Injection

omit:

			Gemcite	ZP	MP		D

[4] Schedule 1 Part 1, entry for Gemcitabine in the form Powder for I.V. infusion 200mg (as hydrochloride) with manner of administration Injection

omit:

			Gemcite	ZP	MP		D

[5] Schedule 1 Part 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL with manner of administration Injection

omit:

Irinotecan	I.V injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	Camptosar	PF	MP	C3184	D
			Hospira Pty Limited	HH	MP	C3184	D

substitute:

Irinotecan	I.V injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	Hospira Pty Limited	HH	MP	C3184	D

[6] Schedule 1 Part 1, entry for Oxaliplatin in the form Powder for I.V. infusion 100mg with manner of administration Injection

omit:

Oxalatin	ZP	MP	C3900 C3901 C3930 C3939	D

[7] Schedule 1 Part 1, entry for Oxaliplatin in the form Powder for I.V. infusion 100mg with manner of administration Injection

omit:

Oxaliplatin Link	PK	MP	C3900 C3901 C3930 C3939	D

[8] Schedule 1 Part 1, entry for Oxaliplatin in the form Powder for I.V. infusion 50mg with manner of administration Injection

omit:

Oxalatin	ZP	MP	C3900 C3901 C3930 C3939	D

[9] Schedule 1 Part 1, entry for Oxaliplatin in the form Powder for I.V. infusion 50mg with manner of administration Injection

omit:

Oxaliplatin Link	PK	MP	C3900 C3901 C3930 C3939	D

[10] Schedule 1 Part 2, entry for Bortezomib

insert after P3767 in the columns in the order indicated:

P7003	3000	15
P7004 P7006	3000	31
P7005 P7007	3000	19

[11] Schedule 2, entry for Folinic acid in the form Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 ml with manner of administration Injection

omit:

Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 ml	Injection	Calcium Folinate Ebewe	SZ	EMP	5	5
		Leucovorin Calcium (Hospira Pty Limited)	HH	EMP	**5**	5
		Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF	EMP	5	5

insert:

Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 ml	Injection	Calcium Folinate Ebewe	SZ	EMP	10	2
		Leucovorin Calcium (Hospira Pty Limited)	HH	EMP	10	2
		Leucovorin Calcium (Pfizer Australia Pty Ltd)	PF	EMP	10	2

[12] Schedule 2, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dehydrate) with manner of administration Oral

omit:

Zondan	GM	EMP	C3050	4	0

[13] Schedule 2, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dehydrate) with manner of administration Oral

omit:

Zondan	GM	EMP	C3050	4	0

[14] Schedule 4, after entry for Bortezomib

insert after C3767:

C7003	P7003	Treatment, in combination with chemotherapy, of a patient with newly diagnosed symptomatic multiple myeloma who is eligible for high dose chemotherapy and autologous stem cell transplantation The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma Authority Application – Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma; and (3) a signed patient acknowledgement A maximum of 4 cycles of treatment with bortezomib will be authorised under this restriction Bortezomib will only be subsidised for patients with multiple myeloma who are not receiving PBS-subsidised thalidomide or lenalidomide	Compliance with written authority required procedures
C7004	P7004	Initial PBS-subsidised treatment in combination with a corticosteroid and melphalan or cyclophosphamide, of a patient with newly diagnosed symptomatic multiple myeloma who is ineligible for high dose chemotherapy The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma and ineligibility for high dose chemotherapy; and (3) a signed patient acknowledgment A maximum of 4 cycles of treatment with bortezomib will be authorised under this restriction Bortezomib will only be subsidised for patients with multiple myeloma who are not receiving PBS-subsidised thalidomide or lenalidomide	Compliance with written authority required procedures
C7005	P7005	Continuing PBS-subsidised treatment in combination with a corticosteroid and melphalan or cyclophosphamide, of a patient with newly diagnosed symptomatic multiple myeloma who is ineligible for high dose chemotherapy and who has received an initial authority prescription for bortezomib and who, at the time of application has demonstrated: (i) no progressive disease; and (ii) has not yet achieved a best confirmed response to bortezomib Authority applications for continuing treatment may be made by telephone Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and this application A maximum of 5 cycles of treatment with bortezomib will be authorised under this restriction Bortezomib will only be subsidised for patients with multiple myeloma who are not receiving PBS-subsidised thalidomide or lenalidomide	Compliance with written or telephone authority required procedures

C7006	P7006	Initial PBS-subsidised treatment, in combination with a corticosteroid and/or cyclophosphamide, of a patient with newly diagnosed symptomatic multiple myeloma who has severe acute renal failure. Patients must require dialysis or be at high risk of requiring dialysis in the opinion of a nephrologist The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma Authority Application – Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response; and (3) a signed patient acknowledgement Disease activity parameters include current diagnostic reports of at least one of the following: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination, i.e. magnetic resonance imaging or computed tomography scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L and urinary Bence-Jones protein undetectable or less than 200 mg per 24 hours) must be provided A maximum of 4 cycles of treatment with bortezomib will be authorised under this restriction Bortezomib will only be subsidised for patients with multiple myeloma who are not receiving PBS-subsidised thalidomide or lenalidomide	Compliance with written authority required procedures
C7007	P7007	Continuing PBS-subsidised treatment in combination with a corticosteroid and/or cyclophosphamide, of a patient with newly diagnosed symptomatic multiple myeloma who has severe acute renal failure and who has received an initial authority prescription for	Compliance with written or telephone authority required procedures

bortezomib and who, at the time of application has demonstrated at least a partial response at the completion of cycle 4
If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:
(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or
(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours
If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:
(c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels
If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:
(d) at least a 50% reduction in bone marrow plasma cells; or
(e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or
(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or
(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L
The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application – Supporting Information form, which includes a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority; and
(3) diagnostic reports demonstrating the patient has achieved at least a partial response
Authority applications for continuing treatment may be faxed to the Chief Executive Medicare. The Chief Executive Medicare will then contact the prescriber by telephone
Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and this application
A maximum of 5 cycles of treatment with bortezomib will be authorised under this restriction
Bortezomib will only be subsidised for patients with multiple myeloma who are not receiving PBS-subsidised thalidomide or lenalidomide

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**.**