PB 124 of 2022

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 12)

National Health Act 1953

I, NIKOLAI TSYGANOV, Assistant Secretary (Acting), Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health and Aged Care, delegate of the Minister for Health and Aged Care, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Date 22 December 2022

NIKOLAI TSYGANOV
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division

Contents

1 Name

(1) This instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2022 (No. 12)*.

(2) This instrument may also be cited as PB 124 of 2022.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	*1 January 2023*	*1 January 2023*

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011 (PB 79 of 2011)

[1] Schedule 1, Part 1, entry for Bortezomib

substitute:

Bortezomib	Powder for injection 1 mg	Injection	Bortezomib Accord	OC	MP	C11099 C13745	D
			Bortezomib Juno	JU	MP	C11099 C13745	D
			DBL Bortezomib	PF	MP	C11099 C13745	D
			Velcade	JC	MP	C11099 C13745	D
	Powder for injection 2.5 mg	Injection	Bortezomib Juno	JU	MP	C11099 C13745	D
			DBL Bortezomib	PF	MP	C11099 C13745	D
	Powder for injection 3 mg	Injection	DBL Bortezomib	PF	MP	C11099 C13745	D
			Velcade	JC	MP	C11099 C13745	D
	Powder for injection 3.5 mg	Injection	Bortezom	CR	MP	C11099 C13745	D
			Bortezomib Accord	OC	MP	C11099 C13745	D
			Bortezomib-AFT	AE	MP	C11099 C13745	D
			Bortezomib Baxter	BX	MP	C11099 C13745	D
			Bortezomib-Dr.Reddy's	RI	MP	C11099 C13745	D
			Bortezomib Juno	JU	MP	C11099 C13745	D
			Bortezomib Sandoz	SZ	MP	C11099 C13745	D
			BORTEZOMIB-TEVA	TB	MP	C11099 C13745	D
			DBL Bortezomib	PF	MP	C11099 C13745	D
			Velcade	JC	MP	C11099 C13745	D

	Solution for injection 2.5 mg in 1 mL	Injection	Bortezomib Accord	OC	MP	C11099 C13745	D
			Bortezomib Ever Pharma	IT	MP	C11099 C13745	D
	Solution for injection 3.5 mg in 1.4 mL	Injection	Bortezomib Accord	OC	MP	C11099 C13745	D
			Bortezomib Ever Pharma	IT	MP	C11099 C13745	D

[2] Schedule 1, Part 1, entry for Cemiplimab

(a) *omit from the column headed "Circumstances":* **C13372**

(b) *insert in numerical order in the column headed "Circumstances":* **C13766**

[3] Schedule 1, Part 1, entry for Daratumumab in each of the forms: Solution concentrate for I.V. infusion 100 mg in 5 mL; and Solution concentrate for I.V. infusion 400 mg in 20 mL

(a) *omit from the column headed "Circumstances":* **C12692**

(b) *insert in numerical order in the column headed "Circumstances":* **C13752**

[4] Schedule 1, Part 1, entry for Doxorubicin - pegylated liposomal in each of the forms: Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL; and Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 50 mg in 25 mL

omit from the column headed "Circumstances" (all instances): **C4786 C4787 C4791**

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

omit:

			Irinotecan Kabi	PK	MP		D

[6] Schedule 1, Part 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 30 mg in 5 mL

omit:

			Paclitaxel Kabi	PK	MP		D

[7] Schedule 1, Part 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 300 mg in 50 mL

omit:

Paclitaxel Kabi	PK	MP		D

[8] Schedule 1, Part 2, entry for Bortezomib

omit from the column headed "Purposes": **P11099**

[9] Schedule 1, Part 2, entry for Cemiplimab *[Maximum Quantity: 350; Number of Repeats: 6]*

(a) *omit from the column headed "Purposes":* **P13372**

(b) *insert in numerical order in the column headed "Purposes":* **P13766**

[10] Schedule 1, Part 2, entry for Daratumumab *[Maximum Quantity: 1920; Number of Repeats: 8]*

omit from the column headed "Purposes": **P12692** *substitute:* **P13752**

[11] Schedule 2, entry for Daratumumab

substitute:

Daratumumab	Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL	Injection	Darzalex SC	JC	MP	C12691 C12842 C12845 C13744 C13751 C13752 C13774	P12845	1	4
					MP	C12691 C12842 C12845 C13744 C13751 C13752 C13774	P12691 P13774	1	5
					MP	C12691 C12842 C12845 C13744 C13751 C13752 C13774	P12842	1	7
					MP	C12691 C12842 C12845 C13744 C13751 C13752 C13774	P13752	1	8
					MP	C12691 C12842 C12845 C13744 C13751 C13752	P13744 P13751	1	15

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C13774

[12] Schedule 4, entry for Bortezomib

insert in numerical order after existing text:

	C13745		Newly diagnosed systemic light chain amyloidosis Administration on Days 1, 8, 15 and 22 of six treatment cycles (28 days per cycle) in total Patient must be undergoing concurrent treatment with PBS-subsidised daratumumab for this PBS indication.	

[13] Schedule 4, entry for Cemiplimab

(a) *omit:*

	C13372	P13372	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 3 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting; AND Patient must not have received prior treatment with a programmed cell death 1 (PD-1) inhibitor or a programmed cell death ligand 1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must express programmed cell death ligand 1 (PD-L1) with a tumour proportion score (TPS) of at least 50% in the tumour sample. The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed a total of 7 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 13372

(b) *insert in numerical order after existing text:*

	C13766	P13766	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 3 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with tepotinib; AND Patient must not have received prior treatment with a programmed cell death 1 (PD-1) inhibitor or a programmed cell death ligand 1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must express programmed cell death ligand 1 (PD-L1) with a tumour proportion score (TPS) of at least 50% in the tumour sample. The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13766

			The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed a total of 7 doses under this restriction.	

[14] Schedule 4, entry for Daratumumab

(a) *omit:*

	C12692	P12692	Relapsed and/or refractory multiple myeloma Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly) The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised). Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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) 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	Compliance with Authority Required procedures

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			(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented 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) must be documented in the patient's medical records. 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) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.	

(b) *insert in numerical order after existing text:*

	C13744	P13744	Newly diagnosed systemic light chain amyloidosis Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be continuing treatment with this drug that was commenced as non-PBS-subsidised supply prior to 1 January 2023; AND The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must have been, prior to the first dose of the non-PBS-subsidised supply, untreated with drug therapy, including this drug, irrespective of whether the diagnosis had been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information; AND Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the date of the histology result, which was within 4 weeks prior to the commencement	Compliance with Written Authority Required procedures

			of non-PBS-subsidised therapy, (ii) the name of pathologist/pathology provider, (iii) the site of biopsy. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Determine an appropriate number of repeat prescriptions for this authority application in line with either: (i) Where the patient has received less than 10 non-PBS-subsidised doses, prescribe a number of repeat prescriptions up to the balance of: 15 doses less the number of non-PBS-subsidised doses; or (ii) Where the patient has received at least 10 non-PBS-subsidised doses, prescribe no more than 5 repeat prescriptions.	
	C13751	P13751	Newly diagnosed systemic light chain amyloidosis Initial treatment from week 0 to week 24 The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis; AND The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis); AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include: Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the date of the histology result, which is no older than 4 weeks at the time of making this authority application, (ii) the name of pathologist/pathology provider, (iii) the site of biopsy. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
	C13752	P13752	Relapsed and/or refractory multiple myeloma Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly) The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised). Patient must be undergoing treatment with this drug in one of the following situations: (i) for the	Compliance with Authority Required procedures

			first time, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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) 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. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented 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) must be documented in the patient's medical records. 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) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity,	

			with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.	
	C13774	P13774	Newly diagnosed systemic light chain amyloidosis Continuing treatment from week 25 onwards (administered once every four weeks) Patient must have previously received PBS-subsidised treatment with this drug for this condition. Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist); AND Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures

[15] Schedule 4, omit entry for Doxorubicin - pegylated liposomal