PB 95 of 2023

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 9)

National Health Act 1953

I, NIKOLAI TSYGANOV, Assistant Secretary, 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 28 September 2023

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

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1 Name

(1) This instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 9)*

(2) This instrument may also be cited as PB 95 of 2023.

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 October 2023*	*1 October 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Carfilzomib in each of the forms: Powder for injection 10 mg; Powder for injection 30 mg; and Powder for injection 60 mg

insert in numerical order in the column headed "Circumstances": **C14363 C14364 C14389**

[2] Schedule 1, Part 1, after entry for Elotuzumab in the form Powder for injection 400 mg

insert:

Enfortumab vedotin	Powder for I.V. infusion 20 mg	Injection	Padcev	LL	MP	C14416	D
	Powder for I.V. infusion 30 mg	Injection	Padcev	LL	MP	C14416	D

[3] Schedule 1, Part 1, entry for Pembrolizumab

insert in numerical order in the column headed "Circumstances": **C14403 C14404 C14405**

[4] Schedule 1, Part 2, entry for Carfilzomib

substitute:

Carfilzomib	P14363 P14364 P14389	60	17
	P12930 P12934	120	17
	P12694 P12849	160	8

[5] Schedule 1, Part 2, after entry for Elotuzumab *[Maximum Amount: 1200; Number of Repeats: 9]*

insert:

Enfortumab vedotin	125	8

[6] Schedule 1, Part 2, entry for Obinutuzumab *[Maximum Amount: 1000; Number of Repeats: 7]*

(a) *omit from the column headed "Purposes":* **P11052**

(b) *insert in numerical order in the column headed "Purposes":* **P14326**

[7] Schedule 1, Part 2, entry for Pembrolizumab *[Maximum Amount: 400; Number of Repeats: 6]*

insert in numerical order in the column headed "Purposes": **P14324 P14403 P14404 P14405**

[8] Schedule 2, after entry for Fosaprepitant

insert:

Fosnetupitant with palonosetron	Solution concentrate for I.V. infusion containing fosnetupitant 235 mg (as chloride hydrochloride) and palonosetron 250 microgram (as hydrochloride)	Injection	Akynzeo IV	JZ	MP	C14387	1	5	C

[9] Schedule 2, entry for Netupitant with Palonosetron

omit from the column headed "Circumstances": **C5991 C5994 C6879 C6937** *substitute:* **C14443**

[10] Schedule 3, after details relevant to Responsible Person code JZ

insert:

LL	Astellas Pharma Australia Pty Ltd	81 147 915 482

[11] Schedule 4, entry for Carfilzomib

insert in numerical order after existing text:

	C14363	P14363	Relapsed and/or refractory multiple myeloma Continuing treatment for Cycles 3 to 12 Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. 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	Compliance with Authority Required procedures - Streamlined Authority Code 14363

		(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.	
C14364	P14364	Relapsed and/or refractory multiple myeloma Continuing treatment for Cycles 13 onwards Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. 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.	Compliance with Authority Required procedures - Streamlined Authority Code 14364
C14389	P14389	Relapsed and/or refractory multiple myeloma Initial treatment for Cycles 1 to 3 The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with lenalidomide and dexamethasone; AND Patient must have progressive disease after at least one prior therapy; AND Patient must not have previously received this drug for this condition. 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	Compliance with Authority Required procedures - Streamlined Authority Code 14389

		(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. Provide details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of the 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 once only through the Authority application for lenalidomide.	

[12] Schedule 4, after entry for Elotuzumab

insert:

Enfortumab vedotin	C14416	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer The condition must have progressed on/following both: (i) platinum-based chemotherapy, (ii) programmed cell death 1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR The condition must have progressed on/following platinum-based chemotherapy, whilst PD-1/PD-L1 inhibitor therapy resulted in an intolerance that required treatment cessation; AND Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Patient must be undergoing treatment with this drug for the first time; OR Patient must be undergoing continuing treatment with this drug, with each of the following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.	Compliance with Authority Required procedures - Streamlined Authority Code 14416

[13] Schedule 4, after entry for Fosaprepitant

insert:

Fosnetupitant with palonosetron	C14387	Nausea and vomiting The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy; AND The treatment must be in combination with dexamethasone, unless contraindicated; AND Patient must be unable to swallow; OR Patient must be contraindicated to oral anti-emetics.	Compliance with Authority Required procedures

[14] Schedule 4, entry for Netupitant with Palonosetron

substitute:

Netupitant with Palonosetron	C14443		Nausea and vomiting The treatment must be in combination with dexamethasone, unless contraindicated; AND The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 14443

[15] Schedule 4, entry for Pembrolizumab

insert in numerical order after existing text:

	C14403	P14403	Advanced carcinoma of the cervix Initial treatment The condition must be at least one of (i) persistent carcinoma, (ii) recurrent carcinoma, (iii) metastatic carcinoma of the cervix; AND The condition must be unsuitable for curative treatment with either of (i) surgical resection, (ii) radiation; AND Patient must have WHO performance status no higher than 1; AND Patient must not have received prior treatment for this PBS indication. Patient must be undergoing concomitant treatment with chemotherapy, containing a minimum of: (i) a platinum-based chemotherapy agent, plus (ii) paclitaxel; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14403
	C14404	P14404	Advanced carcinoma of the cervix Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a total of (i) 24 months, (ii) 35 doses (based on a 3-weekly dose regimen), (iii) 17 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless if it was PBS/non-PBS subsidised. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14404
	C14405	P14405	Advanced carcinoma of the cervix Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must be currently receiving non-PBS-subsidised treatment with this drug for this condition, with treatment having commenced prior to 1 October 2023; AND Patient must have met all other PBS eligibility criteria that a non-Grandfather patient would ordinarily be required to meet, meaning that at the time non-PBS supply was commenced, the	Compliance with Authority Required procedures - Streamlined Authority Code 14405

	patient: (i) had either one of (1) persistent carcinoma, (2) recurrent carcinoma, (3) metastatic carcinoma of the cervix; (ii) had a WHO performance status no higher than 1; (iii) was unsuitable for curative treatment with either of (1) surgical resection, (2) radiation; (iv) had not received prior treatment for this PBS indication; (v) was treated concomitantly with platinum-based chemotherapy agent, plus paclitaxel; AND The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a total of (i) 24 months, (ii) 35 doses (based on a 3-weekly dose regimen), (iii) 17 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless if it was PBS/non-PBS subsidised. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.