PB 89 of 2024

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (September Update) Instrument 2024

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*.

Dated 29 August 2024

NIKOLAI TSYGANOV
Assistant Secretary
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 (September Update) Instrument 2024*

(2) This instrument may also be cited as PB 89 of 2024.

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 September 2024*	*1 September 2024*

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2024 (PB 31 of 2024)

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

omit from the column headed "Circumstances": **C14188**

[2] Schedule 1, Part 1, entry for Trastuzumab in the form Powder for I.V. infusion 60 mg

(a) *omit from the column headed "Circumstances":* **C10293**

(b) *omit from the column headed "Circumstances":* **C10296**

(c) *insert in numerical order in the column headed "Circumstances":* **C15820 C15831**

[3] Schedule 1, Part 1, entry for Trastuzumab in the form Powder for I.V. infusion 150 mg

(a) *omit from the column headed "Circumstances" (all instances):* **C10293**

(b) *omit from the column headed "Circumstances" (all instances):* **C10296**

(c) *insert in numerical order in the column headed "Circumstances" (all instances):* **C15820 C15831**

[4] Schedule 1, Part 1, entry for Trastuzumab in each of the forms: Powder for I.V. infusion 420 mg; and Powder for I.V. infusion 440 mg with diluent

(a) *omit from the column headed "Circumstances":* **C10293**

(b) *omit from the column headed "Circumstances":* **C10296**

(c) *insert in numerical order in the column headed "Circumstances":* **C15820 C15831**

[5] Schedule 1, Part 1, entry for Trastuzumab deruxtecan

omit from the column headed "Circumstances": **C14470** *substitute:* **C15826 C15832**

[6] Schedule 1, Part 1, entry for Trastuzumab emtansine in each of the forms Powder for I.V. infusion 100 mg; and Powder for I.V. infusion 160 mg

omit from the column headed "Circumstances": **C10295 C12989 C13004 C13017** *substitute:* **C15818 C15819 C15827 C15828**

[7] Schedule 1, Part 2, entry for Trabectedin *[Maximum Amount: 3250 mcg; Number of Repeats: 7]*

omit from the column headed "Purposes": **P14188**

[8] **Schedule 1, Part 2, entry for Trastuzumab *[Maximum Amount: 500 mg; Number of Repeats: 0]***

omit from the column headed "Purposes": **P10296** *substitute:* **P15831**

[9] **Schedule 1, Part 2, entry for Trastuzumab *[Maximum Amount: 1000 mg; Number of Repeats: 0]***

(a) *omit from the column headed "Purposes":* **P10293**

(b) *insert in numerical order in the column headed "Purposes":* **P15820**

[10] **Schedule 1, Part 2, entry for Trastuzumab emtansine *[Maximum Amount: 450 mg; Number of Repeats: 6]***

omit from the column headed "Purposes": **P10295 P13004** *substitute:* **P15818 P15819**

[11] **Schedule 1, Part 2, entry for Trastuzumab emtansine *[Maximum Amount: 450 mg; Number of Repeats: 8]***

omit from the column headed "Purposes": **P12989 P13017** *substitute:* **P15827 P15828**

[12] **Schedule 2, entry for Atezolizumab**

insert in numerical order in the column headed "Circumstances" (all instances): **C10917**

[13] **Schedule 2, after entry for Atezolizumab *[Maximum Quantity: 1; Number of Repeats: 7]***

insert:

		C10125 C10206 C10216 C10297 C10521 C10917 C10939 C13443 C13448 C15455	P10917	1	8	

[14] **Schedule 2, entry for Granisetron in the form Concentrated injection 3 mg (as hydrochloride) in 3 mL**

omit:

	Granisetron Kabi	C4139		1	0	V4139

[15] **Schedule 2, after entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Brand: Ondansetron ODT-DRLA]***

insert:

	ONDANSETRON ODT-WGR	C5743		4	0	V5743

[16] Schedule 2, after entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate) *[Brand: Ondansetron Tablets Viatris]*

insert:

	ONDANSETRON-WGR	C5778	4	0	V5778

[17] Schedule 2, after entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Brand: Ondansetron ODT Viatris]*

insert:

	ONDANSETRON ODT-WGR	C5743	4	0	V5743

[18] Schedule 2, after entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate) *[Brand: Ondansetron Tablets Viatris]*

insert:

	ONDANSETRON-WGR	C5778	4	0	V5778

[19] Schedule 3, Part 1, omit entry for Circumstances Code "C10293"

[20] Schedule 3, Part 1, omit entry for Circumstances Code "C10295"

[21] Schedule 3, Part 1, omit entry for Circumstances Code "C10296"

[22] Schedule 3, Part 1, omit entry for Circumstances Code "C12989"

[23] Schedule 3, Part 1, omit entry for Circumstances Code "C13004"

[24] Schedule 3, Part 1, omit entry for Circumstances Code "C13017"

[25] Schedule 3, Part 1, omit entry for Circumstances Code "C14188"

[26] Schedule 3, Part 1, omit entry for Circumstances Code "C14470"

[27] Schedule 3, Part 1, after entry for Circumstances Code "C15527"

insert:

C15818	P15818	Trastuzumab emtansine	Early HER2 positive breast cancer Initial adjuvant treatment	Compliance with Written Authority Required

			The treatment must be prescribed within 12 weeks after surgery; AND Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report; AND Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery. The pathology report must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; 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). Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	procedures
C15819	P15819	Trastuzumab emtansine	Early HER2 positive breast cancer Continuing adjuvant treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	Compliance with Authority Required procedures
C15820	P15820	Trastuzumab	Early HER2 positive breast cancer Initial treatment (3 weekly regimen)	Compliance with Authority Required procedures - Streamlined Authority Code

		Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	15820
C15826	Trastuzumab deruxtecan	Metastatic (Stage IV) HER2 positive breast cancer Patient must have evidence of human epidermal growth factor (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) in either the primary tumour/a metastatic lesion - establish this finding once only with the first PBS prescription; AND The condition must have progressed following treatment with at least one prior HER2 directed regimen for metastatic breast cancer; OR The condition must have, at the time of treatment initiation with this drug, progressed during/within 6 months following adjuvant treatment with a HER2 directed therapy; AND Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only. Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; OR Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions. Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription: 1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable).	Compliance with Authority Required procedures

			2) Details of prior HER2 directed drug regimens prescribed for the patient. 3) Cardiac function test results (evidence obtained in relation to past PBS treatment is acceptable). Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15827	P15827	Trastuzumab emtansine	Metastatic (Stage IV) HER2 positive breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. The treatment must not exceed a lifetime total of one continuous course for this PBS indication. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	Compliance with Authority Required procedures
C15828	P15828	Trastuzumab emtansine	Metastatic (Stage IV) HER2 positive breast cancer Initial treatment Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, confirmed through a pathology report from an Approved Pathology Authority; AND The condition must have progressed following treatment with pertuzumab and trastuzumab in combination; OR The condition must have progressed during or within 6 months of completing adjuvant therapy with trastuzumab; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure. The following information must be provided by the prescriber at the time of application: (a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH).	Compliance with Authority Required procedures

			(b) dates of treatment with trastuzumab and pertuzumab; (c) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or (d) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. All reports must be documented in the patient's medical records. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	
C15831	P15831	Trastuzumab	Early HER2 positive breast cancer Initial treatment (weekly regimen) Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant); AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance. HER2 positivity must be demonstrated by in situ hybridisation (ISH). Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition. Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.	Compliance with Authority Required procedures - Streamlined Authority Code 15831
C15832		Trastuzumab deruxtecan	Unresectable and/or metastatic HER2-low breast cancer Patient must have evidence of human epidermal growth factor receptor 2 (HER2)-low disease; AND Patient must have received prior chemotherapy in the metastatic setting; OR Patient must have developed disease recurrence during or within 6 months of completing adjuvant chemotherapy; AND Patient must have received or be ineligible for endocrine therapy in the metastatic setting, if hormone receptor positive; AND Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND	Compliance with Authority Required procedures

	The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only. Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; OR Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions. HER2-low is defined as an immunohistochemical (IHC) score of 1+ or an IHC score of 2+ and a negative result on in situ hybridization (ISH). Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription: 1) Evidence of HER2-low status 2) Details of prior drug regimens prescribed for the patient 3) Cardiac function test results Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.