PB 60 of 2020

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2020 (No. 6)

National Health Act 1953

I, NATASHA PLOENGES, Assistant Secretary (Acting), Pharmacy Branch, Technology Assessment and Access Division, Department of Health, delegate of the Minister for Health, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 29 June 2020

NATASHA PLOENGES
Assistant Secretary (Acting)
Pharmacy Branch
Technology Assessment and Access Division
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2020 (No. 6)*.

(2) This Instrument may also be cited as PB 60 of 2020.

2 Commencement

This Instrument commences on 1 July 2020.

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

Schedule 1 amends the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011).

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Schedule 1 Amendments

[1] Part 1, Division 1, Section 3, Definition for "diluent fee"

omit: **$5.35** *substitute:* **$5.44**

[2] Part 1, Division 1, Section 3, Definition for "dispensing fee"

omit: **$7.39** *substitute:* **$7.74**

[3] Part 1, Division 1, Section 3, Definition for "distribution fee"

omit: **$27.02** *substitute:* **$27.45**

[4] Part 1, Division 1, Section 3, Definition for "preparation fee"

omit: **$85.06** *substitute:* **$85.78**

[5] Schedule 1, Part 1, entry for Atezolizumab in the form Solution concentrate for I.V. infusion 840 mg in 14 mL

insert in numerical order in the column headed "Circumstances": **C10509**

[6] Schedule 1, Part 1, entry for Atezolizumab in the form Solution concentrate for I.V. infusion 1200 mg in 20 mL

(a) *omit from the column headed "Circumstances":* **C10203**

(b) *insert in numerical order in the column headed "Circumstances":* **C10521**

[7] Schedule 1, Part 1, entry for Bleomycin in the form Powder for injection containing bleomycin sulfate 15,000 I.U.

omit:

	Bleo 15K	JU	MP	C6224 C6275	D

[8] Schedule 1, Part 1, entry for Brentuximab vedotin

(a) *omit from the column headed "Circumstances":* **C6904**

(b) *omit from the column headed "Circumstances":* **C6941**

(c) *insert in numerical order in the column headed "Circumstances":* **C10519 C10524**

[9] Schedule 1, Part 1, entry for Irinotecan in each of the forms: I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL; and I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL

omit:

	IRINOTECAN ACT	JU	MP		D

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[10] Schedule 1, Part 1, entry for Paclitaxel in each of the forms: Solution concentrate for I.V. infusion 30 mg in 5 mL; Solution concentrate for I.V. infusion 100 mg in 16.7 mL; Solution concentrate for I.V. infusion 150 mg in 25 mL; and Solution concentrate for I.V. infusion 300 mg in 50 mL

omit:

				Paclitaxel ACT	JU	MP			D

[11] 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

(a) *omit from the column headed "Circumstances":* **C9599**

(b) *insert in numerical order in the column headed "Circumstances":* **C10510**

[12] Schedule 1, Part 2, entry for Atezolizumab *[Maximum Amount: 1200; Number of Repeats: 4]*

(a) *omit from the column headed "Purposes":* **P10203**

(b) *insert in numerical order in the column headed "Purposes":* **P10521**

[13] Schedule 1, Part 2, entry for Atezolizumab *[Maximum Amount: 1680; Number of Repeats: 3]*

insert in numerical order in the column headed "Purposes": **P10509**

[14] Schedule 1, Part 2, entry for Brentuximab vedotin *[Maximum Amount: 200; Number of Repeats: 11]*

(a) *omit from the column headed "Purposes":* **P6904 P6941**

(b) *insert in numerical order in the column headed "Purposes":* **P10519 P10524**

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

(a) *omit from the column headed "Purposes":* **P9599**

(b) *insert in numerical order in the column headed "Purposes":* **P10510**

[16] Schedule 2, entry for Ondansetron

omit:

	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL	Injection	Ondansetron Alphapharm	AF	MP	C5749	1	0	C
	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL	Injection	Ondansetron Alphapharm	AF	MP	C5749	1	0	C

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[17] Schedule 4, entry for Atezolizumab

(a) *omit:*

	C10203	P10203	Extensive-stage small cell lung cancer Continuing treatment The treatment must be as monotherapy; AND 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10203

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

	C10509	P10509	Extensive-stage small cell lung cancer Continuing treatment - 4 weekly treatment regimen The treatment must be as monotherapy; AND 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10509
	C10521	P10521	Extensive-stage small cell lung cancer Continuing treatment - 3 weekly treatment regimen The treatment must be as monotherapy; AND 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.	Compliance with Authority Required procedures - Streamlined Authority Code 10521

[18] Schedule 4, entry for Brentuximab vedotin

(a) *omit:*

	C6904	P6904	Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) The treatment must not exceed a total of 16 cycles in a lifetime	Compliance with Authority Required procedures

(b) *omit:*

	C6941	P6941	Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)	Compliance with Authority Required procedures

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			The treatment must not exceed a total of 16 cycles in a lifetime	

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

	C10519	P10519	Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles in a lifetime	Compliance with Authority Required procedures
	C10524	P10524	Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles in a lifetime	Compliance with Authority Required procedures

[19] Schedule 4, entry for Ondansetron

omit:

	C5749		Nausea and vomiting The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration. Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.	

[20] Schedule 4, entry for Trastuzumab emtansine

(a) *omit:*

	C9599	P9599	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; 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 as monotherapy; 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. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes: (i) a copy 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) and tick a box to state the person has Stage IV	Compliance with Written Authority Required procedures

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			disease; (ii) dates of treatment with trastuzumab and pertuzumab; and (iii) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab; or (iv) 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. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.	

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

	C10510	P10510	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; 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 as monotherapy; 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. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes: (i) details 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) and tick a box to state the person has Stage IV disease; (ii) dates of treatment with trastuzumab and pertuzumab; and (iii) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or (iv) 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. Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval.	Compliance with Written Authority Required procedures

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