PB 9 of 2014

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 2)

National Health Act 1953

I, FELICITY McNEILL, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 12th February 2014

FELICITY McNEILL
First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 2)*.

(2) This Instrument may also be cited as PB 9 of 2014.

2 Commencement

This Instrument commences on 1 March 2014.

3 Amendment of *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)

Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

[1] Schedule 1, entry for Amino acid formula with vitamins and minerals without phenylalanine

omit:

	Oral powder 400 g (Phenex-2)	Oral	Phenex-2	AB	MP NP	C4295	8	5	1

[2] Schedule 1, entry for Amlodipine in each of the forms: Tablet 5 mg (as besylate); and Tablet 10 mg (as besylate)

omit:

			Amlodipine Pfizer	FZ	MP NP		30	5	30

[3] Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 10; Number of Repeats: 0]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Clavam 875 mg/125 mg	NJ	PDP	C1836 C1837	10	0	10

[4] Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 10; Number of Repeats: 1]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Clavam 875 mg/125 mg	NJ	MP NP	C1836 C1837	10	1	10

[5] Schedule 1, entry for Anastrozole in the form Tablet 1 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Azastrole	ER	MP NP	C2213	30	5	30

[6] Schedule 1, after entry for Aprepitant

insert:

Arachidonic acid and docosahexaenoic acid with carbohydrate	Sachets of oral powder 4 g containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid , 30 (keyomega)	Oral	keyomega	VF	MP NP	C4434	4	5	1

[7] Schedule 1, entry for Bicalutamide in the form Tablet 50 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Bicalox	ER	MP NP	C3674	28	5	28

[8] Schedule 1, after entry for Bimatoprost in the form Eye drops 300 micrograms per mL, 3 mL

insert in the columns in the order indicated:

	Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30	Application to the eye	Lumigan PF	AG	MP AO		1	5	1

[9] Schedule 1, entry for Carbohydrate, fat, vitamins, minerals and trace elements

omit from the column headed "Circumstances": **C1276** *substitute:* **C4438**

[10] Schedule 1, after entry for Carbohydrate, fat, vitamins, minerals and trace elements

insert:

Carbohydrate, fat, vitamins, minerals and trace elements and supplemented with arachidonic acid and docosahexaenoic acid	Sachets containing oral powder 21.5 g, 30 (basecal 100)	Oral	basecal 100	VF	MP NP	C4438	4	5	1
	Sachets containing oral powder 43 g, 30 (basecal 200)	Oral	basecal 200	VF	MP NP	C4438	4	5	1

[11] Schedule 1, entry for Carboplatin in the form Solution for I.V. injection 150 mg in 15 mL

omit:

			Pfizer Australia Pty Ltd	PF	MP		See Note 3	See Note 3	1 D(100)

[12] Schedule 1, entry for Cisplatin in each of the forms: I.V. injection 50 mg in 50 mL; and I.V. injection 100 mg in 100 mL

omit:

			Pfizer Australia Pty Ltd	PF	MP		See Note 3	See Note 3	1 D(100)

[13] Schedule 1, entry for Dicloxacillin in the form Capsule 500 mg (as sodium)

omit:

			Diclocil	BQ	MP NP MW PDP	C1345	24	0	24

[14] Schedule 1, entry for Docetaxel in the form Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent

omit from the column headed "Responsible Person": **YA** *substitute:* **AF**

[15] Schedule 1, after entry for Docetaxel in the form Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent

insert:

Docosahexaenoic acid with carbohydrate	Sachets of oral powder 4 g containing 200 mg docosahexaenoic acid, 30 (docomega)	Oral	docomega	VF	MP NP	C4434	4	5	1	

[16] Schedule 1, entry for Epirubicin in the form Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL

omit:

		Epirubicin Kabi	PK	MP		See Note 3	See Note 3	1	D(100)

[17] Schedule 1, entry for Felodipine in each of the forms: Tablet 2.5 mg (extended release); Tablet 5 mg (extended release); and Tablet 10 mg (extended release)

omit from the column headed "Responsible Person" for the brand "Plendil ER": **AP** *substitute:* **GX**

[18] Schedule 1, entry for Fludarabine in the form Solution for I.V. injection 50 mg fludarabine phosphate in 2 mL

omit:

		AS-Fludarabine	YA	MP	C3887	See Note 3	See Note 3	1	PB(100)

[19] Schedule 1, entry for Gabapentin in each of the forms: Capsule 100 mg; Capsule 300 mg; and Capsule 400 mg

omit:

		Gabapentin Pfizer	FZ	MP NP	C2664	100	5	100	

[20] Schedule 1, entry for Gabapentin in the form Tablet 800 mg

omit:

		Gabapentin Pfizer	FZ	MP NP	C2664	100	5	100	

[21] Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 200 mg (as hydrochloride)

omit:

		Gemcitabine Kabi	PK	MP		See Note 3	See Note 3	1	D(100)

[22] Schedule 1, entry for Gemcitabine in the form Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL

omit:

		Gemcitabine-AS	YA	MP		See Note 3	See Note 3	1	D(100)

[23] Schedule 1, entry for Gemcitabine in the form Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL

omit:

		Gemcitabine-AS	YA	MP			See Note 3	See Note 3	1	D(100)

[24] Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 2 g (as hydrochloride)

omit:

		Gemcitabine Kabi	PK	MP			See Note 3	See Note 3	1	D(100)

[25] Schedule 1, entry for Imiquimod in the form Cream 50 mg per g, 250 mg single use sachets, 12

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

		Aldiq	QA	MP	C4229		1	1	1	

[26] Schedule 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL

omit:

		Irinotecan Kabi	PK	MP	C3184		See Note 3	See Note 3	1	D(100)

[27] Schedule 1, entry for Lactulose in the form Solution BP 3.34 g per 5 mL, 500 mL

(a) *omit:*

		Lactocur	SZ	MP NP	C1150 C1613 C3642 C3643	P3643	3	0	1	

(b) *omit:*

		Lactocur	SZ	MP NP	C1150 C1613 C3642 C3643	P3642	3	3	1	

(c) *omit:*

		Lactocur	SZ	MP NP	C1150 C1613 C3642 C3643	P1150 P1613	1	5	1	

[28] Schedule 1, after entry for Linagliptin

insert:

Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C4423 C4448		60	5	60
	Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C4423 C4448		60	5	60
	Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C4423 C4448		60	5	60

[29] Schedule 1, entry for Lisinopril in the form Tablet 5 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Auro-Lisinopril 5	DO	MP NP		30	5	30		

[30] Schedule 1, entry for Lisinopril in the form Tablet 10 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Auro-Lisinopril 10	DO	MP NP		30	5	30		

[31] Schedule 1, entry for Lisinopril in the form Tablet 20 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Auro-Lisinopril 20	DO	MP NP		30	5	30		

[32] Schedule 1, entry for Mitozantrone in the form Injection 20 mg (as hydrochloride) in 10 mL

omit:

	Pfizer Australia Pty Ltd	PF	MP		See Note 3	See Note 3	1		D(100)

[33] Schedule 1, entry for Nevirapine in the form Tablet 200 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Nevipin	GN	MP See Note 1	C3586 C3587 C3588 C3589	120	5	60		D(100)

[34] Schedule 1, entry for Olanzapine in the form Tablet 2.5 mg

omit:

	Zylap 2.5	QA	MP NP	C1589 C2044	28	5	28		

[35] Schedule 1, entry for Olanzapine in the form Tablet 5 mg

omit:

	Zylap 5	QA	MP NP	C1589 C2044	28	5	28		

[36] Schedule 1, entry for Olanzapine in the form Tablet 7.5 mg

omit:

	Zylap 7.5	QA	MP NP	C1589 C2044	28	5	28		

[37] Schedule 1, entry for Olanzapine in the form Tablet 10 mg

omit:

	Zylap 10	QA	MP NP	C1589 C2044	28	5	28		

[38] Schedule 1, entry for Olanzapine in the form Tablet 5 mg (orally disintegrating)

omit:

	Zylap ODT 5	QA	MP NP	C1589 C2044	28	5	28	

[39] Schedule 1, entry for Olanzapine in the form Tablet 10 mg (orally disintegrating)

omit:

	Zylap ODT 10	QA	MP NP	C1589 C2044	28	5	28	

[40] Schedule 1, entry for Oxaliplatin in the form Solution concentrate for I.V. infusion 50 mg in 10 mL

omit:

	Oxaliplatin Kabi	PK	MP	C3900 C3901 C3930 C3939	See Note 3	See Note 3	1	D(100)

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

omit:

	Taxol	BQ	MP	C3186 C3890 C3902 C3917 C3955 C3956	See Note 3	See Note 3	1	D(100)

[42] Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 100 mg in 16.7 mL

(a) *omit:*

	Paclitaxel Kabi	PK	MP	C3186 C3890 C3902 C3917 C3955 C3956	See Note 3	See Note 3	1	D(100)

(b) *omit:*

	Taxol	BQ	MP	C3186 C3890 C3902 C3917 C3955 C3956	See Note 3	See Note 3	1	D(100)

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

omit:

	Taxol	BQ	MP	C3186 C3890 C3902 C3917 C3955 C3956	See Note 3	See Note 3	1	D(100)

[44] Schedule 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Maximum Quantity: 30; Number of Repeats: 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Topra 40	DO	MP NP	C1177 C1337 C1476 C1533	P1177	30	2	30

[45] Schedule 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Maximum Quantity: 30; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Topra 40	DO	MP NP	C1177 C1337 C1476 C1533	P1337 P1476 P1533	30	5	30

[46] Schedule 1, entry for Pazopanib in the form Tablet 200 mg (as hydrochloride) *[Maximum Quantity: 30; Number of Repeats: 5]*

(a) *insert in numerical order in the column headed "Circumstances":* **C4435 C4439 C4444**

(b) *insert in numerical order in the column headed "Purposes":* **P4439**

[47] Schedule 1, entry for Pazopanib in the form Tablet 200 mg (as hydrochloride) *[Maximum Quantity: 90; Number of Repeats: 2]*

(a) *insert in numerical order in the column headed "Circumstances":* **C4435 C4439 C4444**

(b) *insert in numerical order in the column headed "Purposes":* **P4444**

[48] Schedule 1, entry for Pazopanib in the form Tablet 200 mg (as hydrochloride) *[Maximum Quantity: 90; Number of Repeats: 5]*

(a) *insert in numerical order in the column headed "Circumstances":* **C4435 C4439 C4444**

(b) *insert in numerical order in the column headed "Purposes":* **P4435**

[49] Schedule 1, entry for Pazopanib in the form Tablet 400 mg (as hydrochloride) *[Maximum Quantity: 30; Number of Repeats: 5]*

(a) *insert in numerical order in the column headed "Circumstances":* **C4435 C4439 C4444**

(b) *insert in numerical order in the column headed "Purposes":* **P4439**

[50] Schedule 1, entry for Pazopanib in the form Tablet 400 mg (as hydrochloride) *[Maximum Quantity: 60; Number of Repeats: 2]*

(a) *insert in numerical order in the column headed "Circumstances":* **C4435 C4439 C4444**

(b) *insert in numerical order in the column headed "Purposes":* **P4444**

[51] Schedule 1, entry for Pazopanib in the form Tablet 400 mg (as hydrochloride) *[Maximum Quantity: 60; Number of Repeats: 5]*

(a) *insert in numerical order in the column headed "Circumstances":* **C4435 C4439 C4444**

(b) *insert in numerical order in the column headed "Purposes":* **P4435**

[52] Schedule 1, entry for Quinapril in each of the forms: Tablet 5 mg (as hydrochloride); Tablet 10 mg (as hydrochloride); and Tablet 20 mg (as hydrochloride)

omit:

Quinapril Pfizer	FZ	MP NP			30	5	30

[53] Schedule 1, entry for Risperidone in the form Tablet 0.5 mg *[Maximum Quantity: 60; Number of Repeats: 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rispernia	ER	MP NP	C1589 C2061 C3083	P2061 P3083	60	2	60

[54] Schedule 1, entry for Risperidone in the form Tablet 0.5 mg *[Maximum Quantity: 60; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rispernia	ER	MP NP	C1589 C2061 C3083	P1589	60	5	60

[55] Schedule 1, entry for Risperidone in the form Tablet 1 mg *[Maximum Quantity: 60; Number of Repeats: 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rispernia	ER	MP NP	C1589 C2061 C2272 C3083	P2061 P3083	60	2	60

[56] Schedule 1, entry for Risperidone in the form Tablet 1 mg *[Maximum Quantity: 60; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rispernia	ER	MP NP	C1589 C2061 C2272 C3083	P1589 P2272	60	5	60

[57] Schedule 1, entry for Risperidone in the form Tablet 2 mg *[Maximum Quantity: 60; Number of Repeats: 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rispernia	ER	MP NP	C1589 C2272 C3083	P3083	60	2	60

[58] Schedule 1, entry for Risperidone in the form Tablet 2 mg *[Maximum Quantity: 60; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rispernia	ER	MP NP	C1589 C2272 C3083	P1589 P2272	60	5	60

[59] Schedule 1, entry for Risperidone in the form Tablet 3 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rispernia	ER	MP NP	C1589 C2272		60	5	60

[60] Schedule 1, entry for Risperidone in the form Tablet 4 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rispernia	ER	MP NP	C1589 C2272		60	5	60

[61] Schedule 1, after entry for Saxagliptin

insert:

Saxagliptin with metformin	Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride	Oral	Kombiglyze XR 2.5/1000	BQ	MP NP	C4423 C4451	56	5	56	
	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride	Oral	Kombiglyze XR 5/500	BQ	MP NP	C4423 C4451	28	5	28	
	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride	Oral	Kombiglyze XR 5/1000	BQ	MP NP	C4423 C4451	28	5	28	

[62] Schedule 1, entry for Sertraline in the form Tablet 50 mg (as hydrochloride)

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

			Sertraline Actavis	UA	MP NP	C1211 C1241 C1975	30	5	30	

(b) *omit:*

			Sertraline-GA	UA	MP NP	C1211	30	5	30	

(c) *omit:*

			Sertraline Pfizer	FZ	MP NP	C1211 C1241 C1975	30	5	30	

[63] Schedule 1, entry for Sertraline in the form Tablet 100 mg (as hydrochloride)

(a) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

			Sertraline Actavis	UA	MP NP	C1211 C1241 C1975	30	5	30	

(b) *omit:*

			Sertraline-GA	UA	MP NP	C1211	30	5	30	

(c) *omit:*

			Sertraline Pfizer	FZ	MP NP	C1211 C1241 C1975	30	5	30	

[64] Schedule 1, entry for Somatropin

omit:

	Injection 5 mg (15 i.u.) in 1 mL cartridge (with preservative)	Injection	Genotropin	PF	MP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[65] Schedule 1, entry for Temozolomide in the form Capsule 5 mg *[Maximum Quantity: 5; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Temozolomide Alphapharm	AF	MP	C1736 C1737 C2100 C2101	P1736 P1737 P2101	5	5	5	

[66] Schedule 1, entry for Temozolomide in the form Capsule 5 mg *[Maximum Quantity: 15; Number of Repeats: 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Temozolomide Alphapharm	AF	MP	C1736 C1737 C2100 C2101	P2100	15	2	5	

[67] Schedule 1, entry for Temozolomide in the form Capsule 20 mg *[Maximum Quantity: 5; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Temozolomide Alphapharm	AF	MP	C1736 C1737 C2100 C2101	P1736 P1737 P2101	5	5	5	

[68] Schedule 1, entry for Temozolomide in the form Capsule 20 mg *[Maximum Quantity: 15; Number of Repeats: 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Temozolomide Alphapharm	AF	MP	C1736 C1737 C2100 C2101	P2100	15	2	5	

[69] Schedule 1, entry for Temozolomide in the form Capsule 100 mg *[Maximum Quantity: 5; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Temozolomide Alphapharm	AF	MP	C1736 C1737 C2100 C2101	P1736 P1737 P2101	5	5	5	

[70] Schedule 1, entry for Temozolomide in the form Capsule 100 mg *[Maximum Quantity: 15; Number of Repeats: 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Temozolomide Alphapharm	AF	MP	C1736 C1737 C2100 C2101	P2100	15	2	5	

[71] Schedule 1, entry for Temozolomide in the form Capsule 140 mg *[Maximum Quantity: 5; Number of Repeats: 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Temozolomide Alphapharm	AF	MP	C1736 C1737 C2100 C2101	P1736 P1737 P2101	5	5	5	

[72] Schedule 1, entry for Temozolomide in the form Capsule 140 mg *[Maximum Quantity: 15; Number of Repeats: 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

Temozolomide Alphapharm	AF	MP	C1736 C1737 C2100 C2101	P2100	15	2	5	

[73] Schedule 1, entry for Temozolomide in the form Capsule 250 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Temozolomide Alphapharm	AF	MP	C1736 C1737 C2101	5	5	5	

[74] Schedule 1, entry for Terbutaline

omit:

	Powder for oral inhalation in breath actuated device containing terbutaline sulfate 500 micrograms per dose, 200 doses	Inhalation by mouth	Bricanyl Turbuhaler	AP	MP NP		1	5	1	

[75] Schedule 1, entry for Topotecan in the form Powder for I.V. infusion 4 mg (as hydrochloride)

omit from the column headed "Responsible Person" for the brand "Topotecan Agila": **YA** *substitute:* **AF**

[76] Schedule 1, after entry for Trifluoperazine in the form Tablet 5 mg (as hydrochloride)

insert:

Triglycerides, long chain	Oral liquid 250 mL, 18 (carbzero)	Oral	carbzero	VF	MP NP	C4437	2	5	1

[77] Schedule 1, after entry for Triglycerides, medium chain in the form Oral emulsion 250 mL (Liquigen)

insert in the columns in the order indicated:

	Oral liquid 250 mL, 18 (betaquik)	Oral	betaquik	VF	MP NP	C4443 C4447	2	5	1

[78] Schedule 3, after details relevant to Responsible Person code NI

insert:

NJ	Norac Pharma Australia Pty Ltd	22 164 670 008

[79] Schedule 3

omit:

YA	Agila Australasia Pty Ltd	12 154 055 339

[80] Schedule 4, Part 1, after entry for Aprepitant

insert:

Arachidonic acid and docosahexaenoic acid with carbohydrate	C4434			Peroxisomal biogenesis disorders	Compliance with Authority Required procedures

[81] Schedule 4, Part 1, entry for Carbohydrate, fat, vitamins, minerals and trace elements

substitute:

Carbohydrate, fat, vitamins, minerals and trace elements	C4438			Proven inborn errors of protein metabolism Patient must be unable to meet their energy requirements with permitted food and formulae	

[82] Schedule 4, Part 1, after entry for Carbohydrate, fat, vitamins, minerals and trace elements

insert:

Carbohydrate, fat, vitamins, minerals and trace elements and supplemented with arachidonic acid and docosahexaenoic acid	C4438			Proven inborn errors of protein metabolism Patient must be unable to meet their energy requirements with permitted food and formulae	

[83] Schedule 4, Part 1, after entry for Docetaxel

insert:

Docosahexaenoic acid with carbohydrate	C4434			Peroxisomal biogenesis disorders	Compliance with Authority Required procedures

[84] Schedule 4, Part 1, after entry for Linagliptin

insert:

Linagliptin with metformin	C4423			Diabetes mellitus type 2 Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination	Compliance with Authority Required procedures - Streamlined Authority Code 4423
	C4448			Diabetes mellitus type 2 Continuing treatment Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin	Compliance with Authority Required procedures - Streamlined Authority Code 4448

[85] Schedule 4, Part 1, entry for Pazopanib

insert in numerical order following existing text:

	C4435	P4435		Advanced (unresectable and/or metastatic) soft tissue sarcoma Continuing treatment beyond 3 months Patient must have previously been issued with an authority prescription for pazopanib; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition Applications for continuing therapy may be made by telephone	Compliance with Authority Required procedures
	C4439	P4439		Advanced (unresectable and/or metastatic) soft tissue sarcoma Continuing treatment beyond 3 months Patient must have previously been issued with an authority prescription for pazopanib; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND Patient must require dose adjustment; AND The treatment must be the sole PBS-subsidised therapy for this condition Applications for continuing therapy may be made by telephone	Compliance with Authority Required procedures
	C4444	P4444		Advanced (unresectable and/or metastatic) soft tissue sarcoma Initial treatment Patient must have a WHO performance status of 2 or less; AND Patient must have received prior chemotherapy treatment including an anthracycline; AND Patient must not have received prior treatment with an angiogenesis inhibitor; AND The treatment must be the sole PBS-subsidised therapy for this condition Patient must not have any of the following conditions: adipocytic soft tissue sarcoma; gastrointestinal stromal tumour (GIST); rhabdomyosarcoma other than alveolar or pleomorphic; chondrosarcoma; osteosarcoma; Ewings tumour/primitive neuroectodermal tumour; dermofibromatosis sarcoma protuberans; inflammatory myofibroblastic sarcoma; malignant mesothelioma; mixed mesodermal tumour of the uterus The authority application must be made in writing	Compliance with written Authority Required procedures

[86] Schedule 4, Part 1, after entry for Saxagliptin

insert:

Saxagliptin with metformin	C4423			Diabetes mellitus type 2 Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated	Compliance with Authority Required procedures - Streamlined Authority Code 4423

				Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination	
	C4451			Diabetes mellitus type 2 Continuing treatment Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin	Compliance with Authority Required procedures - Streamlined Authority Code 4451

[87] Schedule 4, Part 1, after entry for Triamcinolone

insert:

Triglycerides, long chain	C4437			Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet; OR Patient must have a glucose transport protein defect; OR Patient must have pyruvate dehydrogenase deficiency Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist	

[88] Schedule 4, Part 1, entry for Triglycerides, medium chain

insert in numerical order following existing text:

	C4443			Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet; OR Patient must have a glucose transport protein defect; OR Patient must have pyruvate dehydrogenase deficiency	Compliance with Authority Required procedures
	C4447			Dietary management of conditions requiring a source of medium chain triglycerides Patient must have chylous ascites; OR Patient must have chylothorax; OR Patient must have hyperlipoproteinaemia type 1; OR Patient must have long chain fatty acid oxidation disorders; OR Patient must have fat malabsorption due to liver disease; OR Patient must have fat malabsorption due to short gut syndrome; OR Patient must have fat malabsorption due to cystic fibrosis; OR Patient must have fat malabsorption due to gastrointestinal disorders	Compliance with Authority Required procedures