



PB 53 of 2013

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 10)

National Health Act 1953

I, ADRIANA PLATONA, First Assistant Secretary (Acting), Pharmaceutical Benefits Division, Department of Health and Ageing, delegate of the Minister for Health, make this Instrument under sections 84AF, 84AK, 85, 85A, 88, 99AEH and 101 of the *National Health Act 1953*.

Dated

9 August 2013

ADRIANA PLATONA

First Assistant Secretary (Acting)
Pharmaceutical Benefits Division
Department of Health and Ageing

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 10)*.

(2) This Instrument may also be cited as PB 53 of 2013.

2 Commencement

This Instrument commences on 1 September 2013.

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 Apixaban

substitute:

Apixaban	Tablet 2.5 mg	Oral	Eliquis	BQ	MP NP	C3957 C3991 C4043 C4044 C4046 C4269	P3957 P4043	20	0	20	
					MP NP	C3957 C3991 C4043 C4044 C4046 C4269	P3991 P4044	30	0	30	
					MP NP	C3957 C3991 C4043 C4044 C4046 C4269	P4046	60	0	60	
					MP NP	C3957 C3991 C4043 C4044 C4046 C4269	P4269	60	5	60	
	Tablet 5 mg	Oral	Eliquis	BQ	MP NP	C4269		60	5	60	

[2] Schedule 1, entry for Buprenorphine with naloxone

omit:

	Tablet (sublingual) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride)	Sublingual	Suboxone	RC	MP NP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)
	Tablet (sublingual) 8 mg (as hydrochloride)-2 mg (as hydrochloride)	Sublingual	Suboxone	RC	MP NP See Note 1	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)

[3] Schedule 1, entry for Candesartan with Hydrochlorothiazide in the form Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg

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

	Candesartan/ HCT Sandoz	SZ	MP NP	C3307		30	5	30	
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(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

	Pharmacor Candesartan HCT 16/12.5	CR	MP NP	C3307		30	5	30	
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[4] Schedule 1, entry for Candesartan with Hydrochlorothiazide in the form Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg

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

Candesartan/ HCT Sandoz	SZ	MP NP	C3307	30	5	30
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(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

Pharmacor Candesartan HCT 32/12.5	CR	MP NP	C3307	30	5	30
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[5] Schedule 1, entry for Candesartan with Hydrochlorothiazide in the form Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg

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

Candesartan/ HCT Sandoz	SZ	MP NP	C3307	30	5	30
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(b) *insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

Pharmacor Candesartan HCT 32/25	CR	MP NP	C3307	30	5	30
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[6] Schedule 1, entry for Cefepime in each of the forms: Powder for injection 1 g (as hydrochloride); and Powder for injection 2 g (as hydrochloride)

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

Cefepime-AFT	AE	MP NP	C1427	10	0	1
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[7] Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg

(a) *omit:*

Cyprohexal	SZ	MP	C1014 C1230 C1404	P1230	20	5	20
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(b) *omit:*

Cyprohexal	SZ	MP	C1014 C1230 C1404	P1014 P1404	100	5	50
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[8] Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg

omit:

Cyprohexal	SZ	MP	C1014 C1404		50	5	50
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[9] Schedule 1, entry for Dabigatran etexilate

omit:

Capsule 110 mg (as mesilate)	Oral	Pradaxa	BY	MP NP	C3957 C4047 C4048	P3957	20	0	10
				MP NP	C3957 C4047 C4048	P4047	20	1	10
				MP NP	C3957 C4047 C4048	P4048	60	0	60

substitute:

Capsule 110 mg (as mesilate)	Oral	Pradaxa	BY	MP NP	C3957 C4047 C4048 C4269	P3957	20	0	10
				MP NP	C3957 C4047 C4048 C4269	P4047	20	1	10
				MP NP	C3957 C4047 C4048 C4269	P4048	60	0	60
				MP NP	C3957 C4047 C4048 C4269	C4269	60	5	60
Capsule 150 mg (as mesilate)	Oral	Pradaxa	BY	MP NP	C4269		60	5	60

**[10] Schedule 1, entry for Duloxetine in each of the forms Capsule 30 mg (as hydrochloride); and Capsule 60 mg (as hydrochloride)
[Manner of Administration Oral; Brand Duloxetine DR GH]**

omit from "Duloxetine DR GH" in the column headed "Brand":

DR

[11] Schedule 1, entry for Famciclovir in the form Tablet 250 mg [Maximum Quantity 21; Number of Repeats 0]

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

Auro-Famciclovir 250	DO	MP NP	C3622 C3623	P3622	21	0	21
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[12] Schedule 1, entry for Famciclovir in the form Tablet 250 mg [Maximum Quantity 56; Number of Repeats 5]

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

Auro-Famciclovir 250	DO	MP NP	C3622 C3623	P3623	56	5	56
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[13] Schedule 1, after entry for Filgrastim in the form Injection 300 micrograms in 0.5 mL single use pre-filled syringe (TevaGrastim)

insert in the columns in the order indicated:

Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Zarzio)	Injection	Zarzio	SZ	MP See Note 1	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921	20	11	5	D(100)
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	C2922 C2923
	C2924 C2925
	C2926 C2927
	C2928 C2929
	C2930 C3087
	C3187 C3357
	C3358 C3359
	C3360 C3361
	C3362 C3363
	C3364 C3365
	C3366 C3367
	C3368 C3369
	C3370 C3371
	C3372 C3373
	C3374 C3375
	C3376 C3377
	C3833 C3834

[14] Schedule 1, after entry for Filgrastim in the form Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Nivestim)

insert in the columns in the order indicated:

Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Zarzio)	Injection	Zarzio	SZ	MP See Note 1	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834	20	11	5	D(100)
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[15] Schedule 1, after entry for Flutamide in the form Tablet 250 mg

insert:

Tablet 250 mg, 30	Oral	Flutamide MYLAN	AF	MP NP	C3674	3	5	1
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[16] Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 200 mg (as hydrochloride)

omit:

Gemzar	LY	MP	See Note 3	See Note 3	1	D(100)
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[17] Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 1 g (as hydrochloride)

omit:

Gemzar	LY	MP	See Note 3	See Note 3	1	D(100)
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[18] Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 2 g (as hydrochloride)

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

Gemcitabine Actavis 2000	WQ	MP	See Note 3	See Note 3	1	D(100)
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[19] Schedule 1, entry for Granisetron in the form Concentrated injection 3 mg (as hydrochloride) in 3 mL

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

Granisetron-AFT	AE	MP NP	C4077 C4092	1	0	1
		See Note 1	See Note 2	See Note 2	See Note 2	

[20] Schedule 1, entry for Hydroxychloroquine

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

Hydroxychloro quine Actavis	GM	MP NP	100	1	100
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[21] Schedule 1, entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg

omit:

Formet 500	QA	MP NP	100	5	100
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[22] Schedule 1, entry for Metformin in the form Tablet containing metformin hydrochloride 850 mg

omit:

Formet 850	QA	MP NP	60	5	60
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[23] Schedule 1, entry for Misoprostol

omit:

Cytotec	PF	MP	C2630 C2631 C2632	120	2	120
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[24] Schedule 1, entry for Montelukast in the form Tablet, chewable, 4 mg (as sodium)

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

Pharmacor Montelukast 4	CR	MP NP	C2617	28	5	28
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[25] Schedule 1, entry for Montelukast in the form Tablet, chewable, 5 mg (as sodium)

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

Pharmacor Montelukast 5	CR	MP NP	C2618 C3217	28	5	28
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[26] Schedule 1, entry for Norfloxacin

omit:

Noroxin	MK	MP NP	C1002 C1070	14	1	14
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[27] Schedule 1, entry for Ondansetron in each of the forms: I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL; and I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL

omit:

Zofran	AS	MP NP See Note 1	C3050 C3611 See Note 2	See Note 2	1 See Note 2	0 See Note 2	1
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[28] Schedule 1, entry for Paclitaxel in each of the forms: Solution concentrate for I.V. infusion 30 mg in 5 mL; and Solution concentrate for I.V. infusion 100 mg in 16.7 mL

omit:

Paclitaxel Pfizer	PF	MP	C3186 C3890 C3902 C3917 C3955 C3956	See Note 3	See Note 3	1	D(100)
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[29] Schedule 1, entry for Quinapril in the form Tablet 5 mg (as hydrochloride)

omit:

Acquin 5	QA	MP NP		30	5	30
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[30] Schedule 1, entry for Quinapril in the form Tablet 10 mg (as hydrochloride)

omit:

Acquin 10	QA	MP NP		30	5	30
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[31] Schedule 1, entry for Quinapril in the form Tablet 20 mg (as hydrochloride)

omit:

Acquin 20	QA	MP NP	30	5	30
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[32] Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated)

(a) *omit:*

Rabeprazole Actavis 20	TA	MP NP	C1177 C1337 C1533	P1177	30	2	30
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(b) *omit:*

Rabeprazole Actavis 20	TA	MP NP	C1177 C1337 C1533	P1337 P1533	30	5	30
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[33] Schedule 1, entry for Raltegravir

substitute:

Raltegravir	Tablet 25 mg (as potassium)	Oral	Isentress	MK	MP See Note 1	C4273 C4274 C4275 C4276	360	5	60	D(100)
	Tablet 100 mg (as potassium)	Oral	Isentress	MK	MP See Note 1	C4273 C4274 C4275 C4276	360	5	60	D(100)
	Tablet 400 mg (as potassium)	Oral	Isentress	MK	MP See Note 1	C3586 C3587 C3588 C3589	120	5	60	D(100)

[34] Schedule 1, entry for Risedronic Acid and Calcium in the form Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium 500 mg (as carbonate)

omit:

Actonel Combi	SW	MP NP	C4122 C4123 C4133	1	5	1
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[35] Schedule 1, entry for Salbutamol

omit:

Nebuliser solution 5 mg (as sulfate) per mL, 30 mL	Inhalation	Pfizer Australia Pty Ltd	PF	MP NP	C1754 C1755	2	2	1
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[36] Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate)

omit:

Sumagran 50	QA	MP NP	C3233	4	5	2
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[37] Schedule 1, after entry for Tadalafil

insert:

Tafluprost	Eye drops 15 micrograms per mL, single dose units 0.3 mL, 30	Application to the eye	Saflutan	MK	MP	AO	1	5	1
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[38] Schedule 4, Part 1, entry for Apixaban

insert in numerical order following existing text:

	C4269	P4269		<p>Prevention of stroke or systemic embolism</p> <p>Patient must have non-valvular atrial fibrillation</p> <p>Patient must have one or more risk factors for developing stroke or systemic embolism</p> <p>Risk factors for developing stroke or systemic ischaemic embolism are:</p> <p>(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;</p> <p>(ii) age 75 years or older;</p> <p>(iii) hypertension;</p> <p>(iv) diabetes mellitus;</p> <p>(v) heart failure and/or left ventricular ejection fraction 35% or less</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4269
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[39] Schedule 4, Part 1, entry for Dabigatran etexilate

insert in numerical order following existing text:

	C4269	P4269		<p>Prevention of stroke or systemic embolism</p> <p>Patient must have non-valvular atrial fibrillation</p> <p>Patient must have one or more risk factors for developing stroke or systemic embolism</p> <p>Risk factors for developing stroke or systemic ischaemic embolism are:</p> <p>(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;</p> <p>(ii) age 75 years or older;</p> <p>(iii) hypertension;</p> <p>(iv) diabetes mellitus;</p> <p>(v) heart failure and/or left ventricular ejection fraction 35% or less</p>	Compliance with Authority Required procedures - Streamlined Authority Code 4269
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[40] Schedule 4, Part 1, entry for Misoprostol

omit:

	C2630			Reduction in the incidence of gastrointestinal complications in patients who have a history of peptic ulcer disease and where non-steroidal anti-inflammatory drug therapy is essential	Compliance with Authority Required procedures - Streamlined Authority Code 2630
	C2631			Duodenal ulcer (including pyloric and stomal ulcers), proven by current or prior x-ray, endoscopy or surgery, where the date on which, and the method by which, the ulcer was proven are documented in the patient's medical records when treatment is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 2631

	C2632			Gastric ulcer, proven by x-ray, endoscopy or surgery within the previous 2 years, where the date on which, and the method by which, the ulcer was proven are documented in the patient's medical records when treatment is initiated	Compliance with Authority Required procedures - Streamlined Authority Code 2632
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[41] Schedule 4, Part 1, entry for Raltegravir

insert in numerical order following existing text:

	C4273			Where the patient is receiving treatment at/from a private hospital HIV infection Continuing treatment The treatment must be in combination with other antiretroviral agents, Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, Patient must have previously received PBS-subsidised therapy for HIV infection, Patient must be aged 2 years or older	Compliance with Written and Telephone Authority Required procedures
	C4274			Where the patient is receiving treatment at/from a public hospital HIV infection Continuing treatment The treatment must be in combination with other antiretroviral agents, Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, Patient must have previously received PBS-subsidised therapy for HIV infection, Patient must be aged 2 years or older	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4274
	C4275			Where the patient is receiving treatment at/from a public hospital HIV infection Initial treatment The treatment must be in combination with other antiretroviral agents, Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, Patient must have a CD4 count of less than 500 per cubic millimetre; OR Patient must have symptomatic HIV disease, Patient must be aged 2 years or older	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4275
	C4276			Where the patient is receiving treatment at/from a private hospital HIV infection Initial treatment The treatment must be in combination with other antiretroviral agents, Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, Patient must have a CD4 count of less than 500 per cubic millimetre; OR Patient must have symptomatic HIV disease, Patient must be aged 2 years or older	Compliance with Written and Telephone Authority Required procedures