

Pharmaceutical Management Agency

Section H Update for Hospital Pharmaceuticals

Effective 1 September 2016

Cumulative for August and September 2016



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Summary of decisions

EFFECTIVE 1 SEPTEMBER 2016

- Amino acid formula (Vivonex Paediatric) powder 6 g protein, 31.5 g carbohydrate and 5.88 g fat per sachet, 48.5 g – to be delisted 1 April 2017
- Amisulpride (Sulprix) tab 100 mg, 200 mg and 400 mg – new listing and addition of HSS
- Amisulpride (Solian) tab 100 mg, 200 mg and 400 mg – to be delisted 1 November 2016
- Atorvastatin (Lorstat) tab 10 mg, 20 mg, 40 mg and 80 mg – new listing and addition of HSS
- Atorvastatin (Zarator) tab 10 mg, 20 mg, 40 mg and 80 mg – to be delisted 1 November 2016
- Atracurium besylate (Tracrium) inj 10 mg per ml, 2.5 ml and 5 ml ampoules – HSS suspended
- Bacillus calmette-guerin (BCG) (SII-Onco-BCG) inj 40 mg per ml, vial – to be delisted 1 February 2017
- Cefalexin (Cephalexin ABM) cap 250 mg – new listing and addition of HSS
- Ceftriaxone (DEVA) inj 500 mg and 1 g vials – new listing and addition of HSS
- Ceftriaxone (Ceftriaxone-AFT) inj 500 mg and 1 g vials – to be delisted 1 November 2016
- Chlorhexidine (Baxter) irrigation soln 0.02%, bottle, 100 ml – price increase
- Chlorhexidine (Baxter) irrigation soln 0.05%, bottle, 100 ml and 500 ml – price increase
- Chlorhexidine (Baxter) irrigation soln 0.1%, bottle, 100 ml – price increase
- Chlorhexidine (Baxter) irrigation soln 0.5%, bottle, 500 ml – to be delisted 1 September 2016
- Chlorhexidine with cetrimide (Baxter) irrigation soln 0.015% with cetrimide 0.15%, bottle, 100 ml and 500 ml – price increase
- Chlorhexidine with cetrimide (Baxter) irrigation soln 0.05% with cetrimide 0.5%, bottle, 500 ml – price increase
- Chlorhexidine with cetrimide (Baxter) irrigation soln 0.1% with cetrimide 1%, bottle, 100 ml – price increase
- Chlorhexidine with cetrimide (Baxter) irrigation soln 0.05% with cetrimide 0.5%, bottle, 100 ml – Pharmacode change and price increase
- Chlorhexidine with cetrimide (Baxter) irrigation soln 0.1% with cetrimide 1%, bottle, 500 ml – to be delisted 1 September 2016
- Chlorpromazine hydrochloride oral liq 20 mg per ml – new listing

Summary of decisions – effective 1 September 2016 (continued)

- Clobetasol propionate (Dermol) crm 0.05%, 30 g and oint 0.05%, 30 g – new listing and addition of HSS
 - Clobetasol propionate (Clobetasol BNM) crm 0.05% and oint 0.05% – to be delisted 1 December 2016
 - Clotrimazole (Clomazol) vaginal crm 1% with applicator, 35 g – price increase and addition of HSS
 - Clotrimazole (Clomazol) vaginal crm 2% with applicator, 20 g – price decrease and addition of HSS
 - Compound electrolytes (Baxter) inj sodium 140 mmol/l with potassium 5 mmol/l, magnesium 1.5 mmol/l, chloride 98 mmol/l, acetate 27 mmol/l and gluconate 23 mmol/l, bag 500 ml – Pharmacode change
 - Compound electrolytes (Baxter) Inj sodium 140 mmol/l with potassium 5 mmol/l, magnesium 1.5 mmol/l, chloride 98 mmol/l, acetate 27 mmol/l and gluconate 23 mmol/l, bag 1,000 ml – Pharmacode change and price decrease
 - Dabigatran (Pradaxa) cap 75 mg, 110 mg and 150 mg – price decrease
 - Desflurane (Suprane) soln for inhalation 100%, 240 ml bottle – price decrease and addition of HSS
 - Enoxaparin sodium (Clexane) inj syringe 20 mg in 0.2 ml, 40 mg in 0.4 ml, 60 mg in 0.6 ml, 80 mg in 0.8 ml, 100 mg in 1 ml, 120 mg in 0.8 ml and 150 mg in 1 ml – chemical name change and price decrease
 - Glucose [dextrose] (Baxter) inj 5%, bag 50 ml and 250 ml – Pharmacode change
 - Glucose [dextrose] (Baxter) inj 10%, bag 500 ml and 1,000 ml – price increase
 - Glucose [dextrose] (Baxter) inj 50% bag 500 ml – price increase
 - Glucose with potassium chloride (Baxter) inj 5% glucose with 20 mmol/l potassium chloride, bag 1,000 ml – price increase
 - Glucose with potassium chloride and sodium chloride (Baxter) inj 4% glucose with potassium chloride 20 mmol/l and sodium chloride 0.18%, bag 1,000 ml – price increase
 - Glucose with potassium chloride and sodium chloride (Baxter) inj 4% glucose with potassium chloride 30 mmol/l and sodium chloride 0.18%, bag 1,000 ml – price increase
 - Glucose with sodium chloride (Baxter) inj glucose 2.5% with sodium chloride 0.45%, bag 500 ml – price increase
 - Glucose with sodium chloride (Baxter) inj glucose 5% with sodium chloride 0.9%, bag 1,000 ml – price increase
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Summary of decisions – effective 1 September 2016 (continued)

- Glucose with sodium chloride (Baxter) inj glucose 5% with sodium chloride 0.45%, bag 500 ml – to be delisted 1 September 2016
- Glycine (Baxter) irrigation soln 1.5%, bottle, 2,000 ml and 3,000 ml – price increase
- Idarucizumab (Praxbind) inj 50 mg per ml, 50 ml vial – new listing
- Isoflurane (Aerrane) soln for inhalation 100%, 250 ml bottle – price decrease and addition of HSS
- Malathion with permethrin and piperonyl butoxide spary 0.25% with permethrin 0.5% and piperonyl butoxide 2% – to be delisted 1 January 2017
- Mannitol (Baxter) inj 10%, 1,000 ml bag – price increase
- Mannitol (Baxter) inj 15%, 500 ml bag – to be delisted 1 September 2016
- Mannitol (Baxter) inj 20%, 500 ml bag – price increase
- Mesna (Uromitexan) inj 100 mg per ml, 4 ml and 10 ml ampoules – price decrease
- Nicotine (Habitrol (Classic)) gum 2 mg and 4 mg – to be delisted 1 March 2017
- Nivolumab (Opdivo) inj 10 mg per ml, 4 ml and 10 ml vial – amended restriction
- Pembrolizumab (Keytruda) inj 50 mg vial – new listing
- Plerixafor (Mozobil) inj 20 mg per ml, 1.2 ml vial – new listing
- Posaconazole (Noxafil) tab modified-release 100 mg – new listing
- Potassium chloride with sodium chloride (Baxter) inj 20 mmol/l potassium chloride with 0.9% sodium chloride, bag 1,000 ml – price increase
- Potassium chloride with sodium chloride (Baxter) inj 30 mmol/l potassium chloride with 0.9% sodium chloride, bag 1,000 ml – price increase
- Potassium chloride with sodium chloride (Baxter) inj 40 mmol/l potassium chloride with 0.9% sodium chloride, bag 1,000 ml – Pharmacode change and price increase
- Pyridostigmine bromide (Mestinon) tab 60 mg – price increase and addition of HSS
- Ringer’s solution (Baxter) inj sodium 147 mmol/l with potassium 4 mmol/l, calcium 2.2 mmol/l, chloride 156 mmol/l, bag 1,000 ml – price increase
- Risperidone (Risperdal Quicklet) tab orodispersible 0.5 mg, 1 mg and 2 mg – to be delisted 1 June 2017
- Sevoflurane (Baxter) soln for inhalation 100%, 250 ml bottle – price decrease and addition of HSS

Summary of decisions – effective 1 September 2016 (continued)

- Sodium chloride (Baxter) irrigation soln 0.9%, bottle, 100 ml, 500 ml, 1,000 ml and 3,000 ml – price increase
- Sodium chloride (Baxter) irrigation soln 0.9%, bottle, 2,000 ml – Pharmacode change and price increase
- Temozolomide (Temaccord) cap 5 mg, 20 mg, 100 mg and 250 mg – amended restriction
- Vecuronium bromide inj 4 mg ampoule – to be delisted 1 September 2016
- Water (Baxter) irrigation soln, bottle, 100 ml, 500 ml and 1,000 ml – price increase
- Water (Baxter) irrigation soln, bottle, 2,000 ml and 3,000 ml – Pharmacode change and price increase
- Zoledronic acid (Zoledronic acid Mylan) inj 4 mg per 5 ml, vial – new listing

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Section H changes to Part II

Effective 1 September 2016

BLOOD AND BLOOD FORMING ORGANS

30	IDARUCIZUMAB (new listing) → Inj 50 mg per ml, 50 ml vial.....	4,250.00	2	Praxbind
	Restricted Initiation For the reversal of the anticoagulant effects of dabigatran when required in situations of life-threatening or uncontrolled bleeding, or for emergency surgery or urgent procedures.			
33	ENOXAPARIN SODIUM (chemical name change and ↓ price)			
	Inj 20 mg in 0.2 ml syringe	30.91	10	Clexane
	Inj 40 mg in 0.4 ml syringe	41.24	10	Clexane
	Inj 60 mg in 0.6 ml syringe	62.18	10	Clexane
	Inj 80 mg in 0.8 ml syringe	82.88	10	Clexane
	Inj 100 mg in 1 ml syringe	103.80	10	Clexane
	Inj 120 mg in 0.8 ml syringe	128.98	10	Clexane
	Inj 150 mg in 1 ml syringe	147.41	10	Clexane
33	DABIGATRAN (↓ price)			
	Cap 75 mg	76.36	60	Pradaxa
	Cap 110 mg	76.36	60	Pradaxa
	Cap 150 mg	76.36	60	Pradaxa
36	PLERIXAFOR (new listing) → Inj 20 mg per ml, 1.2 ml vial.....	8,740.00	1	Mozobil
	Restricted Initiation – autologous stem cell transplant Haematologist <i>Limited to 3 days treatment</i> All of the following: 1. Patient is to undergo stem cell transplantation; and 2. Patient has not had a previous unsuccessful mobilisation attempt with plerixafor; and 3. Any of the following: 3.1 Both: 3.1.1 Patient is undergoing G-CSF mobilisation; and 3.1.2 Either: 3.1.2.1 Has a suboptimal peripheral blood CD34 count of $\leq 10 \times 10^6/L$ on day 5 after 4 days of G-CSF treatment; or 3.1.2.2 Efforts to collect $> 1 \times 10^6$ CD34 cells/kg have failed after one apheresis procedure; or 3.2 Both: 3.2.1 Patient is undergoing chemotherapy and G-CSF mobilisation; and 3.2.2 Any of the following: 3.2.2.1 Has rising white blood cell counts of $> 5 \times 10^9/L$ and a suboptimal peripheral blood CD34 count of $\leq 10 \times 10^6/L$; or 3.2.2.2 Efforts to collect $> 1 \times 10^6$ CD34 cells/kg have failed after one apheresis procedure; or 3.2.2.3 The peripheral blood CD34 cell counts are decreasing before the target has been received; or 3.3 A previous mobilisation attempt with G-CSF or G-CSF plus chemotherapy has failed.			

		Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
Changes to Section H Part II – effective 1 September 2016 (continued)				
36	COMPOUND ELECTROLYTES (Pharmacode change) Inj sodium 140 mmol/l with potassium 5 mmol/l, magnesium 1.5 mmol/l, chloride 98 mmol/l, acetate 27 mmol/l and gluconate 23 mmol/l, bag	5.00	500 ml	Baxter
	Note – Pharmacode change from 2076764 to 2474212.			
36	COMPOUND ELECTROLYTES (Pharmacode change and † price) Inj sodium 140 mmol/l with potassium 5 mmol/l, magnesium 1.5 mmol/l, chloride 98 mmol/l, acetate 27 mmol/l and gluconate 23 mmol/l, bag	2.40	1,000 ml	Baxter
	Note – Pharmacode change from 610089 to 2474220.			
37	GLUCOSE [DEXTROSE] (Pharmacode change) Inj 5%, bag	2.87	50 ml	Baxter
		3.87	250 ml	Baxter
	Note – Pharmacode change for 50 ml bag from 2232197 to 2076519, and for 250 ml bag from 2076276 to 466131.			
37	GLUCOSE [DEXTROSE] († price) Inj 10%, bag	6.11	500 ml	Baxter
		9.33	1,000 ml	Baxter
	Inj 50%, bag	18.74	500 ml	Baxter
37	GLUCOSE WITH POTASSIUM CHLORIDE († price) Inj 5% glucose with 20 mmol/l potassium chloride, bag	12.09	1,000 ml	Baxter
37	GLUCOSE WITH POTASSIUM CHLORIDE AND SODIUM CHLORIDE († price) Inj 4% glucose with potassium chloride 20 mmol/l and sodium chloride 0.18%, bag	8.31	1,000 ml	Baxter
	Inj 4% glucose with potassium chloride 30 mmol/l and sodium chloride 0.18%, bag	10.74	1,000 ml	Baxter
37	GLUCOSE WITH SODIUM CHLORIDE († price) Inj glucose 2.5% with sodium chloride 0.45%, bag	8.12	500 ml	Baxter
	Inj glucose 5% with sodium chloride 0.9%, bag	8.92	1,000 ml	Baxter
37	GLUCOSE WITH SODIUM CHLORIDE (delisting) Inj glucose 5% with sodium chloride 0.45%, bag	9.87	500 ml	Baxter
	Note – Baxter glucose with sodium chloride inj glucose 5% with sodium chloride 0.45%, bag 500 ml to be delisted from 1 September 2016.			
38	POTASSIUM CHLORIDE WITH SODIUM CHLORIDE († price) Inj 20 mmol/l potassium chloride with 0.9% sodium chloride, bag	7.66	1,000 ml	Baxter
	Inj 30 mmol/l potassium chloride with 0.9% sodium chloride, bag	9.40	1,000 ml	Baxter
38	POTASSIUM CHLORIDE WITH SODIUM CHLORIDE (Pharmacode change and † price) Inj 40 mmol/l potassium chloride with 0.9% sodium chloride, bag	12.26	1,000 ml	Baxter
	Note – Pharmacode change from 2232103 to 2478374.			

→ Restriction

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	Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 September 2016 (continued)

38	RINGER'S SOLUTION († price) Inj sodium 147 mmol/l with potassium 4 mmol/l, calcium 2.2 mmol/l, chloride 156 mmol/l, bag	8.69	1,000 ml	Baxter
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CARDIOVASCULAR SYSTEM

47	MANNITOL († price) Inj 10%, 1,000 ml bag	24.85	1,000 ml	Baxter
	Inj 20%, 500 ml bag	23.08	500 ml	Baxter

47	MANNITOL (delisting) Inj 15%, 500 ml bag	9.84	500 ml	Baxter
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Note – Baxter mannitol inj 15%, 500 ml bag to be delisted from 1 September 2016.

48	ATORVASTATIN (brand change) Tab 10 mg – 1% Nov-16 to 2018	9.29	500	Lorstat
	Tab 20 mg – 1% Nov-16 to 2018	13.32	500	Lorstat
	Tab 40 mg – 1% Nov-16 to 2018	21.23	500	Lorstat
	Tab 80 mg – 1% Nov-16 to 2018	36.26	500	Lorstat

Note – Zarator tab 10 mg, 20 mg, 40 mg and 80 mg to be delisted from 1 November 2016.

DERMATOLOGICALS

54	MALATHION WITH PERMETHRIN AND PIPERONYL BUTOXIDE (delisting) Spray 0.25% with permethrin 0.5% and piperonyl butoxide 2% Note – Malathion with permethrin and piperonyl butoxide spray 0.25% with permethrin 0.5% and piperonyl butoxide 2% to be delisted from 1 January 2017.			
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56	CLOBETASOL PROPIONATE (brand change) Crm 0.05% – 1% Dec-16 to 2019	2.20	30 g	Dermol
	Oint 0.05% – 1% Dec-16 to 2019	2.20	30 g	Dermol

Note – Clobetasol BNM crm 0.05% and oint 0.05% to be delisted from 1 December 2016.

GENITO-URINARY SYSTEM

59	CLOTRIMAZOLE (addition of HSS) Vaginal crm 1% with applicator – 1% Nov-16 to 2019 († price)	1.60	35 g	Clomazol
	Vaginal crm 2% with applicator – 1% Nov-16 to 2019 (↓ price)	2.10	20 g	Clomazol

HORMONE PREPARATIONS

64	ZOLEDRONIC ACID (new listing) → Inj 4 mg per 5 ml, vial	84.50	1	Zoledronic acid Mylan
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		Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 September 2016 (continued)

INFECTIONS

74	CEFALEXIN (new listing) Cap 250 mg – 1% Dec-16 to 2019	3.50	20	Cephalexin ABM
74	CEFTRIAXONE (brand change) Inj 500 mg vial – 1% Nov-16 to 2019 Inj 1 g vial – 1% Nov-16 to 2019	1.20 0.84	1 1	DEVA DEVA
Note – Ceftriaxone-AFT inj 500 mg and 1 g vials to be delisted from 1 November 2016.				
80	POSACONAZOLE (new listing) ➔ Tab modified-release 100 mg	869.86	24	Noxafil

MUSCULOSKELETAL SYSTEM

97	PYRIDOSTIGMINE BROMIDE (↑ price and addition of HSS) Tab 60 mg – 1% Nov-16 to 2019	42.79	100	Mestinon
104	ATRACURIUM BESYLATE (HSS suspended) Inj 10 mg per ml, 2.5 ml ampoule – 1% DV Jan-16 to 2018 31/8/16 Inj 10 mg per ml, 5 ml ampoule – 1% DV Jan-16 to 2018 31/8/16	10.00 12.50	5 5	Tracrium Tracrium
104	VECURONIUM BROMIDE (delisting) Inj 4 mg ampoule Note – Vecuronium bromide inj 4 mg ampule delisted from 1 September 2016.			

NERVOUS SYSTEM

108	DESFLURANE (↓ price and addition of HSS) Soln for inhalation 100%, 240 ml bottle – 1% Sep-16 to 2019	1,350.00	6	Suprane
108	ISOFLURANE (↓ price and addition of HSS) Soln for inhalation 100%, 250 ml bottle – 1% Sep-16 to 2019	1,020.00	6	Aerrane
109	SEVOFLURANE (↓ price and addition of HSS) Soln for inhalation 100%, 250 ml bottle – 1% Sep-16 to 2019	840.00	6	Baxter
123	AMISULPRIDE (brand change) Tab 100 mg – 1% Nov-16 to 2019 Tab 200 mg – 1% Nov-16 to 2019 Tab 400 mg – 1% Nov-16 to 2019	4.56 14.75 27.70	30 60 60	Sulprix Sulprix Sulprix
Note Solian tab 100 mg, 200 mg and 400 mg to be delisted from 1 November 2016.				
124	CHLORPROMAZINE HYDROCHLORIDE (new listing) Oral liq 20 mg per ml			

➔ Restriction

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Changes to Section H Part II – effective 1 September 2016 (continued)

125	RISPERIDONE (delisting)			
	→ Tab orodispersible 0.5 mg	21.42	28	Risperdal Quicklet
	→ Tab orodispersible 1 mg	42.84	28	Risperdal Quicklet
	→ Tab orodispersible 2 mg	85.71	28	Risperdal Quicklet
	Note – Risperdal Quicklet tab orodispersible 0.5 mg, 1 mg and 2 mg to be delisted from 1 June 2017.			
133	NICOTINE (discontinuation)			
	Gum 2 mg – 1% DV Apr-14 to 2017	22.26	384	Habitrol (Classic)
	Gum 4 mg – 1% DV Apr-14 to 2017	25.67	384	Habitrol (Classic)
	Note – Habitrol (Classic) gum 2 mg and 4 mg to be delisted from 1 March 2017. Habitrol gum 2 mg and 4 mg in Fruit and Mint flavours remain listed.			

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

138	TEMOZOLOMIDE (restriction change)			
	→ Cap 5 mg	8.00	5	Temaccord
	→ Cap 20 mg	36.00	5	Temaccord
	→ Cap 100 mg	175.00	5	Temaccord
	→ Cap 250 mg	410.00	5	Temaccord
	Restricted			
	Initiation – High grade gliomas			
	Re-assessment required after 12 months			
	All of the following:			
	1 Either:			
	1.1 Patient has newly diagnosed glioblastoma multiforme; or			
	1.2 Patient has newly diagnosed anaplastic astrocytoma*; and			
	2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and			
	3 Following concomitant treatment temozolomide is to be used for a maximum of 5 days treatment per cycle six cycles of 5 days treatment , at a maximum dose of 200 mg/m ² per day.			
	Initiation — Neuroendocrine tumours			
	Re-assessment required after 9 months			
	All of the following:			
	1 Patient has been diagnosed with metastatic or unresectable well-differentiated neuroendocrine tumour*; and			
	2 Temozolomide is to be given in combination with capecitabine; and			
	3 Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a maximum dose of 200 mg/m ² per day; and			
	4 Temozolomide to be discontinued at disease progression.			
	Continuation – High grade gliomas			
	Re-assessment required after 12 months			
	Either:			
	1. Both:			
	1.1. Patient has glioblastoma multiforme; and			
	1.2. The treatment remains appropriate and the patient is benefitting from treatment; or			
	2. All of the following			
	2.1. Patient has anaplastic astrocytoma*; and			
	2.2. The treatment remains appropriate and the patient is benefitting from treatment; and			
	2.3. Adjuvant temozolomide is to be used for a maximum of 24 months.			
	Continuation — Neuroendocrine tumours			
	Re-assessment required after 6 months			
	Both:			
	1 No evidence of disease progression; and			

continued...

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 September 2016 (continued)

continued...

2 The treatment remains appropriate and the patient is benefitting from treatment.

Note: Indication marked with a * is an Unapproved Indication. Temozolomide is not funded for the treatment of relapsed glioblastoma multiforme.

144	MESNA (↓ price)			
	Inj 100 mg per ml, 4 ml ampoule – 1% DV Oct-16 to 2019	161.25	15	Uromitexan
	Inj 100 mg per ml, 10 ml ampoule – 1% DV Oct-16 to 2019	370.35	15	Uromitexan
178	BACILLUS CALMETTE-GUERIN (BCG) (delisting)			
	→ Inj 40 mg per ml, vial	149.37	3	SII-Onco-BCG
	Note – SII-Onco-BCG inj 40 mg per ml, vial to be delisted from 1 February 2017.			
178	NIVOLUMAB (amended restriction)			
	→ Inj 10 mg per ml, 4 ml vial	1,051.98	1	Opdivo
	→ Inj 10 mg per ml, 10 ml vial	2,629.96	1	Opdivo
	Restricted Initiation Medical oncologist <i>Re-assessment required after 4 months</i> All of the following:			
	1 Patient has metastatic or unresectable melanoma stage III or IV; and			
	2 Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion; and			
	3 Either:			
	3.1 Patient has not received funded pembrolizumab; or			
	3.2 Both:			
	3.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and			
	3.2.2 The cancer did not progress while the patient was on pembrolizumab; and			
	43 Nivolumab is to be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles); and			
	54 Baseline measurement of overall tumour burden is documented (see Note); and			
	65 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of nivolumab will not be continued beyond 12 weeks (6 cycles) if their disease progresses during this time.			
	Continuation Medical oncologist <i>Re-assessment required after 4 months</i> All of the following:			
	1 Any of the following:			
	1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or			
	1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or			
	1.3 Patient has stable disease according to RECIST criteria (see Note); and			
	2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and			
	3 No evidence of progressive disease according to RECIST criteria (see Note); and			
	4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and			
	5 Nivolumab will be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles).			

Notes:

Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST)

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→ Restriction

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	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 September 2016 (continued)

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version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks.

Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

178 PEMBROLIZUMAB (new listing)

→ Inj 50 mg vial 2,340.00 1 Keytruda

Restricted

Initiation

Medical oncologist

Re-assessment required after 4 months

All of the following:

- 1 Patient has metastatic or unresectable melanoma stage III or IV; and
- 2 Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion; and
- 3 Either:
 - 3.1 Patient has not received funded nivolumab; or
 - 3.2 Both:
 - 3.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
 - 3.2.2 The cancer did not progress while the patient was on nivolumab; and
- 4 Pembrolizumab is to be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles); and
- 5 Baseline measurement of overall tumour burden is documented (see Note); and
- 6 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of pembrolizumab will not be continued beyond 12 weeks (4 cycles) if their disease progresses during this time.

Continuation

Medical oncologist

Re-assessment required after 4 months

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
 - 1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
 - 1.3 Patient has stable disease according to RECIST criteria (see Note); and
- 2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and
- 3 No evidence of progressive disease according to RECIST criteria (see Note); and
- 4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and

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	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 September 2016 (continued)

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- 5 Pembrolizumab is to be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles).

Notes:

Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks.

Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

VARIOUS

199	CHLORHEXIDINE (↑ price)			
	Irrigation soln 0.02%, bottle	6.20	100 ml	Baxter
	Irrigation soln 0.05%, bottle	7.83	100 ml	Baxter
		7.37	500 ml	Baxter
	Irrigation soln 0.1%, bottle	8.71	100 ml	Baxter
199	CHLORHEXIDINE (delisting)			
	Irrigation soln 0.5%, bottle	4.69	500 ml	Baxter
	Note – Baxter chlorhexidine irrigation soln 0.5%, bottle 500 ml to be delisted from 1 September 2016.			
199	CHLORHEXIDINE WITH CETRIMIDE (↑ price)			
	Irrigation soln 0.015% with cetrimide 0.15%, bottle	6.04	100 ml	Baxter
		9.55	500 ml	Baxter
	Irrigation soln 0.05% with cetrimide 0.5%, bottle	12.14	500 ml	Baxter
	Irrigation soln 0.1% with cetrimide 1%, bottle	10.00	100 ml	Baxter
199	CHLORHEXIDINE WITH CETRIMIDE (Pharmacode change and ↑ price)			
	Irrigation soln 0.05% with cetrimide 0.5%, bottle	9.31	100 ml	Baxter
	Note – Pharmacode change from 2076152 to 2084430.			
199	CHLORHEXIDINE WITH CETRIMIDE (delisting)			
	Irrigation soln 0.1% with cetrimide 1%, bottle	5.81	500 ml	Baxter
	Note – Baxter chlorhexidine with cetrimide irrigation soln 0.1% with cetrimide 1%, bottle 500 ml to be delisted from 1 September 2016.			

→ Restriction

(Brand) indicates a brand example only. It is not a contracted product.

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 September 2016 (continued)

199	GLYCINE († price)			
	Irrigation soln 1.5%, bottle	19.48	2,000 ml	Baxter
		22.70	3,000 ml	Baxter
199	SODIUM CHLORIDE († price)			
	Irrigation soln 0.9%, bottle	5.22	100 ml	Baxter
		6.19	500 ml	Baxter
		6.59	1,000 ml	Baxter
		19.26	3,000 ml	Baxter
199	SODIUM CHLORIDE (Pharmacode change and † price)			
	Irrigation soln 0.9%, bottle	15.11	2,000 ml	Baxter
	Note – Pharmacode change from 785091 to 307122.			
199	WATER († price)			
	Irrigation soln, bottle	5.24	100 ml	Baxter
		5.94	500 ml	Baxter
		6.58	1,000 ml	Baxter
199	WATER (Pharmacode change and † price)			
	Irrigation soln, bottle	16.47	2,000 ml	Baxter
		29.21	3,000 ml	Baxter
	Note – Pharmacode change for 2,000 ml bag from 2076799 to 761958, and for 3,000 ml bag from 2076780 to 2089963.			

SPECIAL FOODS

212	AMINO ACID FORMULA			
	→ Powder 6 g protein, 31.5 g carbohydrate and 5.88 g fat per sachet	6.00	48.5 g	Vivonex Paediatric
	Note – Vivonex Paediatric powder to be delisted from 1 April 2017.			

PART I – GENERAL RULES

- 7 HOSPITAL SUPPLY OF PHARMACEUTICALS
- 2 Hospital Pharmaceuticals
- 2.1 Section H Part II contains the list of Hospital Pharmaceuticals that must be funded by DHB Hospitals. Section H Part II does not currently encompass the following categories of pharmaceuticals except for any items specifically listed in this Section H Part II:
- Medical Devices;
 - whole or fractionated blood products;
 - diagnostic products which have an ex vivo use, such as pregnancy tests and reagents;
 - disinfectants and sterilising products, except those that are to be used in or on a patient;
 - foods and probiotics;
 - radioactive materials;
 - medical gases; and
 - parenteral nutrition; **and**
 - pharmaceutical products for in-vivo investigation of allergy.**
- Subject to rule 2.2, the funding of pharmaceuticals identified in a)–i) above is a decision for individual DHB Hospitals.

		Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 August 2016

ALIMENTARY TRACT AND METABOLISM

13	LOPERAMIDE HYDROCHLORIDE (new listing) Tab 2 mg – 1% DV Oct-16 to 2019	10.75	400	Nodia
14	SULPHASALAZINE (↑ price and addition of HSS) Tab 500 mg – 1% DV Oct-16 to 2019	14.00	100	Salazopyrin
	Tab EC 500 mg – 1% DV Oct-16 to 2019	13.50	100	Salazopyrin EN
23	FERROUS SULPHATE (↑ price and addition of HSS) Oral liq 30 mg (6 mg elemental) per ml – 1% DV Oct-16 to 2019	10.80	500 ml	Ferodan
26	COLECALCIFEROL CHOLECALCIFEROL (amended chemical name) Cap 1.25 mg (50,000 iu)	3.85	12	Vit.D3

BLOOD AND BLOOD FORMING ORGANS

38	SODIUM CHLORIDE (amended presentation description, ↑ price and addition of HSS) Inj 23.4% (4 mmol/ml), 20 ml ampoule – 1% DV Oct-16 to 2019	33.00	5	Biomed
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CARDIOVASCULAR SYSTEM

43	AMIODARONE HYDROCHLORIDE (new listing) Tab 100 mg – 1% DV Oct-16 to 2019	4.66	30	Cordarone X
	Tab 200 mg – 1% DV Oct-16 to 2019	7.63	30	Cordarone X
44	LABETALOL (↑ price) Tab 50 mg	8.99	100	Hybloc
	Tab 100 mg	11.36	100	Hybloc
	Tab 200 mg	29.74	100	Hybloc
44	METOPROLOL SUCCINATE (HSS delayed) Tab long-acting 23.75 mg – 1% DV Nov-16 Jan-17 to 2018	2.39	90	Metoprolol - AFT CR
	Tab long-acting 47.5 mg – 1% DV Nov-16 Jan-17 to 2018	3.48	90	Metoprolol - AFT CR
	Tab long-acting 95 mg – 1% DV Nov-16 Jan-17 to 2018	5.73	90	Metoprolol - AFT CR
	Tab long-acting 190 mg – 1% DV Nov-16 Jan-17 to 2018	11.54	90	Metoprolol - AFT CR
45	SOTALOL (↑ price and addition of HSS) Tab 80 mg – 1% DV Oct-16 to 2019	39.53	500	Mylan
	Tab 160 mg – 1% DV Oct-16 to 2019	12.48	100	Mylan
47	INDAPAMIDE (↑ price and addition of HSS) Tab 2.5 mg – 1% DV Oct-16 to 2019	2.60	90	Dapa-Tabs
47	SPIRONOLACTONE (addition of HSS) Tab 25 mg – 1% DV Oct-16 to 2019 (↑ price)	4.38	100	Spiractin
	Tab 100 mg – 1% DV Oct-16 to 2019	11.80	100	Spiractin

➔ Restriction

(Brand) indicates a brand example only. It is not a contracted product.

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 August 2016 (continued)

49	ISOSORBIDE MONONITRATE († price) Tab long-acting 60 mg	8.49	90	Duride
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DERMATOLOGICALS

54	PHENOTHRIN (new listing) Shampoo 0.5%			
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GENITO-URINARY SYSTEM

60	LEVONORGESTREL (new listing) → Intra-uterine system, 20 mcg per day – 1% DV Aug-16 to 2019	269.50	1	Mirena e.g. Mirena
60	MEDROXYPROGESTERONE ACETATE († price and addition of HSS) Inj 150 mg per ml, 1 ml syringe – 1% DV Oct-16 to 2019	7.25	1	Depo-Provera

61	PROGESTERONE (amended restriction) → Cap 100 mg – 1% DV Aug-16 to 2019	16.50	30	Utrogestan
	Restricted Initiation Gynaecologist or obstetrician Re-assessment required after 12 months Both: 1 For the prevention of pre-term labour*; and 2 Either: 2.1 The patient has a short cervix on ultrasound (defined as < 25mm at 16 to 28 weeks); or 2.2 The patient has a history of pre-term birth at less than 28 weeks.			

Continuation

Gynaecologist or obstetrician

Re-assessment required after 12 months

All of the following:

1. For the prevention of pre-term labour*; and
2. Treatment is required for second or subsequent pregnancy; and
3. Either:
 - 3.1. The patient has a short cervix on ultrasound (defined as < 25 mm at 16 to 28 weeks); or
 - 3.2. The patient has a history of pre-term birth at less than 28 weeks.

Note: Indications marked with * are Unapproved Indications (refer to Section A: General Rules, Part I (Interpretations and Definitions) and Part IV (Miscellaneous Provisions) rule 23.1)

HORMONE PREPARATIONS

64	HYDROCORTISONE († price and addition of HSS) Inj 100 mg vial – 1% DV Oct-16 to 2019	5.30	1	Solu-Cortef
66	MEDROXYPROGESTERONE ACETATE († price and addition of HSS) Tab 2.5 mg – 1% DV Oct-16 to 2019	3.75	30	Provera
	Tab 5 mg – 1% DV Oct-16 to 2019	14.00	100	Provera
	Tab 10 mg – 1% DV Oct-16 to 2019	7.15	30	Provera

		Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 August 2016 (continued)

65	OESTRADIOL (new listing)			
	Patch 25 mcg per day – 1% DV Oct-16 to 2019	6.12	8	Estradot
	Patch 50 mcg per day – 1% DV Oct-16 to 2019	7.04	8	Estradot
	Patch 100 mcg per day – 1% DV Oct-16 to 2019	7.91	8	Estradot
66	MEDROXYPROGESTERONE (↑ price, addition of HSS and amended brand name)			
	Tab 100 mg – 1% DV Oct-16 to 2019	101.00	100	Provera HD Provera

INFECTIONS

74	CEFALEXIN (↓ price and addition of HSS)			
	Cap 500 mg – 1% DV Oct-16 to 2019	3.95	20	Cephalexin ABM
83	RIFABUTIN (↑ price and addition of HSS)			
	→ Cap 150 mg – 1% DV Oct-16 to 2019	275.00	30	Mycobutin
84	ORNIDAZOLE (↑ price and addition of HSS)			
	Tab 500 mg – 1% DV Oct-16 to 2019	23.00	10	Arrow-Ornidazole
85	QUININE SULPHATE (↑ price)			
	Tab 300 mg	61.91	500	Q 300
86	NEVIRAPINE (↑ price)			
	→ Oral suspension 10 mg per ml.....	203.55	240 ml	Viramune Suspension

MUSCULOSKELETAL SYSTEM

97	PENICILLAMINE (↑ price)			
	Tab 125 mg	67.23	100	D-Penaminate
	Tab 250 mg	110.12	100	D-Penaminate
98	ALENDRONATE SODIUM WITH COLECALCIFEROL CHOLECALCIFEROL (chemical name and presentation description amendment)			
	→ Tab 70 mg with colecalfiferol cholecalciferol 5,600 iu.....	12.90	4	Fosamax Plus

NERVOUS SYSTEM

113	MORPHINE TARTRATE (↑ price, addition of HSS and amended brand name)			
	Inj 80 mg per ml, 1.5 ml ampoule – 1% DV Oct-16 to 2019	42.72	5	DBL Morphine Tartrate Hospira
115	DOTHIEPIN HYDROCHLORIDE (↑ price)			
	Tab 75 mg	11.19	100	Dopress
	Cap 25 mg	6.45	100	Dopress
116	FLUOXETINE HYDROCHLORIDE (addition of HSS)			
	Tab dispersible 20 mg, scored			
	– 1% DV Oct-16 to 2019 (↓ price)	2.47	30	Arrow-Fluoxetine
	Cap 20 mg – 1% DV Oct-16 to 2019 (↑ price)	1.99	90	Arrow-Fluoxetine

→ Restriction

(Brand) indicates a brand example only. It is not a contracted product.

		Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 August 2016 (continued)

123	AMISULPRIDE (↑ price and addition of HSS) Oral liq 100 mg per ml – 1% DV Oct-16 to 2019	65.53	60 ml	Solian
123	ONDANSETRON (HSS and delisting delayed) Inj 2 mg per ml, 4 ml ampoule – 1% DV Nov-16 Sep-16 to 2019	2.20	5	Ondansetron Kabi
Note – HSS for Ondansetron-Kabi has been delayed and will now begin from 1 November 2016. The delisting of Ondanaccord inj 2 mg per ml, 4 ml ampoule will also be delayed until 1 November 2016.				
124	HALOPERIDOL (addition of HSS) Tab 500 mcg – 1% DV Oct-16 to 2019	6.23	100	Serenace
	Tab 1.5 mg – 1% DV Oct-16 to 2019	9.43	100	Serenace
	Tab 5 mg – 1% DV Oct-16 to 2019	29.72	100	Serenace
	Oral liq 2 mg per ml – 1% DV Oct-16 to 2019	23.84	100 ml	Serenace
	Inj 5 mg per ml, 1ml ampoule – 1% DV Oct-16 to 2019	21.55	10	Serenace

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

135	MITOMYCIN C (↑ price and addition of HSS) Inj 5 mg vial – 1% DV Oct-16 to 2019	204.08	1	Arrow
136	METHOTREXATE (↑ price, addition of HSS and amended brand name) Inj 25 mg per ml, 2 ml vial – 1% DV Oct-16 to 2019	30.00	5	DBL Methotrexate Onco-Vial Hospira
	Inj 25 mg per ml, 20 ml vial – 1% DV Oct-16 to 2019	45.00	1	DBL Methotrexate Onco-Vial Hospira
137	DACARBAZINE (↑ price, addition of HSS and amended brand name) Inj 200 mg vial – 1% DV Oct-16 to 2019	58.06	1	DBL Decarbazine Hospira
138	TEMOZOLOMIDE (amended restriction) → Cap 5 mg.....	8.00	5	Temaccord
	→ Cap 20 mg.....	36.00	5	Temaccord
	→ Cap 100 mg.....	175.00	5	Temaccord
	→ Cap 250 mg.....	410.00	5	Temaccord

Restricted

Initiation – High grade gliomas

All of the following:

- 1 Either:
 - 1.1 Patient has newly diagnosed glioblastoma multiforme; or
 - 1.2 Patient has newly diagnosed anaplastic astrocytoma*; and
- 2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and
- 3 Following concomitant treatment temozolomide is to be used for a maximum of six cycles of 5 days treatment, at a maximum dose of 200 mg/m².

Initiation – Neuroendocrine tumours

Re-assessment required after 9 months

All of the following:

1. Patient has been diagnosed with metastatic or unresectable well-differentiated neuroendocrine tumour*;
and
2. Temozolomide is to be given in combination with capecitabine; and

continued...

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 August 2016 (continued)

continued...

3. Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a maximum dose of 200 mg/m² per day; and
4. Temozolomide to be discontinued at disease progression.

Continuation – Neuroendocrine tumours

Re-assessment required after 6 months

Both:

1. No evidence of disease progression; and
2. The treatment remains appropriate and the patient is benefitting from treatment.

Note: Indication marked with a * is an Unapproved Indication. Temozolomide is not funded for the treatment of relapsed glioblastoma multiforme. Reapplications will not be approved. Studies of temozolomide show that its benefit is predominantly in those patients with a good performance status (WHO grade 0 or 1 or Karnofsky score >= 80), and in patients who have had at least a partial resection of the tumour.

144	MESNA (↑ price and addition of HSS)			
	Tab 400 mg – 1% DV Oct-16 to 2019	273.00	50	Uromitexan
	Tab 600 mg – 1% DV Oct-16 to 2019	407.50	50	Uromitexan
	Inj 100 mg per ml, 4 ml ampoule – 1% DV Oct-16 to 2019	161.37	15	Uromitexan
	Inj 100 mg per ml, 10 ml ampoule – 1% DV Oct-16 to 2019	370.49	15	Uromitexan
144	VINCRIStINE SULPHATE (↑ price, addition of HSS and amended brand name)			
	Inj 1 mg per ml, 1 ml vial – 1% DV Oct-16 to 2019	74.52	5	DBL Vincristine Sulfate Hospira
	Inj 1 mg per ml, 2 ml vial – 1% DV Oct-16 to 2019	85.61	5	DBL Vincristine Sulfate Hospira

RESPIRATORY SYSTEM AND ALLERGIES

180	BECLOMETHASONE DIPROPIONATE (↑ price)			
	Nasal spray 50 mcg per dose	5.26	200 dose	Alanase
	Nasal spray 100 mcg per dose	6.00	200 dose	Alanase
181	BUDESONIDE (↑ price)			
	Nasal spray 50 mcg per dose	5.26	200 dose	Butacort Aqueous
	Nasal spray 100 mcg per dose	6.00	200 dose	Butacort Aqueous
181	PROMETHAZINE HYDROCHLORIDE (↑ price and addition of HSS)			
	Inj 25 mg per ml, 2 ml ampoule – 1% DV Oct-16 to 2019	15.54	5	Hospira

SENSORY ORGANS

187	ACICLOVIR (new listing)			
	Eye oint 3% – 1% DV Oct-16 to 2019	14.92	4.5 g	ViruPOS

SPECIAL FOODS

216	HIGH ARGININE ORAL FEED 1.4 KCAL/ML (new listing)			
	→ Liquid 10.1 g protein, 15 g carbohydrate, 4.5 g fat and 0 g fibre per 100 ml, carton	4.00	178 ml	Impact Advanced Recovery

→ Restriction

(Brand) indicates a brand example only. It is not a contracted product.

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 August 2016 (continued)

216	HIGH ARGININE ORAL FEED 1.4 KCAL/ML (delisting)			
	→ Liquid 7.6 g protein, 18.9 g carbohydrate, 3.9 g fat and 1.4 g fibre per 100 ml, carton	4.00	237 ml	Impact Advanced Recovery (Chocolate) Impact Advanced Recovery (Vanilla)

Note – Impact Advanced Recovery (Chocolate and Vanilla), 237 ml to be delisted 1 February 2017.

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