Pharmaceutical Management Agency

# Section H Update for Hospital Pharmaceuticals

**Effective 1 October 2016** 

**Cumulative for August, September and October 2016** 



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## Summary of decisions EFFECTIVE 1 OCTOBER 2016

- Aspirin (Ethics Aspirin EC) tab 100 mg price increase and addition of HSS
- Aspirin (Ethics Aspirin) tab dispersible 300 mg new listing and addition of HSS
- Boceprevir (Victrelis) cap 200 mg to be delisted 1 April 2017
- Cetirizine hydrochloride (Zista) tab 10 mg new listing and addition of HSS
- Cetirizine hydrochloride (Zetop) tab 10 mg to be delisted 1 December 2016
- Cilazapril (Apo-Cilazapril) tab 2.5 mg and 5 mg new listing and addition of HSS
- Cilazapril (Zapril) tab 2.5 mg and 5 mg to be delisted 1 December 2016
- Cinacalcet (Sensipar) tab 30 mg amended restriction
- Coal tar (Midwest) soln BP, 200 ml new listing and addition of HSS
- Compound electrolytes (Enerlyte) powder for oral soln new listing and addition of HSS
- Disopyramide phosphate cap 150 mg to be delisted 1 April 2017
- Enteral feed 1 kcal/ml (Jevity RTH) liquid 4 g protein, 14.1 g carbohydrate, 3.47 g fat and 1.76 g fibre per 100 ml, bottle, 500 ml – to be delisted 1 June 2017
- Enteral feed 1 kcal/ml (Jevity) liquid 4 g protein, 14.1 g carbohydrate, 3.47 g fat and 1.76 g fibre per 100 ml, can, 237 ml to be delisted 1 June 2017
- Fludarabine phosphate (Fludarabine Ebewe) inj 50 mg vial addition of HSS
- Fluphenazine decanoate (e.g. Modecate) inj 25 mg per ml, 2 ml ampoule to be delisted 1 December 2016
- Ganciclovir (e.g. Virgan) eye gel 0.15% to be delisted 1 November 2016
- Goserelin (Zoladex) implant 3.6 mg, syringe and implant 10.8 mg, syringe
   amended presentation, price decrease and addition of HSS
- Hydrocortisone (Pharmacy Health) crm 1%, 500 g price increase, addition of HSS and addition of DV Limit note
- Ipratropium bromide (Univent) nebuliser soln 250 mcg per ml, 1 ml and 2 ml ampoules – price increase and addition of HSS
- Leuprorelin acetate (Lucrin and Eligard) various presentations amended presentation descriptions and brand names
- Midazolam (Midazolam-Claris) inj 1 mg per ml, 5 ml ampoule and inj 5 mg per ml, 3 ml ampoule – new listing and addition of HSS
- Midazolam (Hypnovel and Pfizer) inj 1 mg per ml, 5 ml ampoule and inj 5 mg per ml, 3 ml ampoule – to be delisted 1 December 2016

#### Summary of decisions – effective 1 October 2016 (continued)

- Oral feed (Ensure (Chocolate)) powder 16 g protein, 57.4 g carbohydrate and 14 g fat per 100 g, can, 850 g new listing of a new formulation
- Oral feed (Ensure Plus (chocolate)) liquid 5.5 g protein, 21.1 g carbohydrate and 4.81 g fat per 100 ml, can, 237 ml to be delisted 1 April 2017
- Pancreatic enzyme amended presentation descriptions
- Pantoprazole (Panzop Relief) tab EC 20 mg and 40 mg new listing and addition of HSS
- Pantoprazole tab EC 20 mg (Pantoprazole Actavis 20) and tab EC 40 mg (Pantoprazole Actavis 40) – to be delisted 1 December 2016
- Salbutamol (Salamol) aerosol inhaler, 100 mcg per dose to be delisted 1 April 2017

Price Brand or (ex man. Excl. GST) Generic \$ Per Manufacturer

## **Section H changes to Part II**

Effective 1 October 2016

#### **ALIMENTARY TRACT AND METABOLISM**

ALIIV	ENIARY IRACI AND WEIADULISW		
16	PANTOPRAZOLE (brand change)  Tab EC 20 mg – 1% DV Dec-16 to 2019	100 100 ab EC 40 m	Panzop Relief Panzop Relief g to be delisted from
18	PANCREATIC ENZYME  Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase 10,000  Ph Eur U, total protease 600 Ph Eur U) EC-10,000 BP u lipase, 9,000 BP u amylase and 210 BP u protease  — 1% DV Oct-15 to 2018	100	Creon 10000
	- 1% DV Oct-15 to 2018	100	Creon 25000
BLOC	DD AND BLOOD FORMING ORGANS		
35	ASPIRIN († price and addition of HSS) Tab 100 mg – <b>10% DV Dec-16 to 2019</b> 12.50	990	Ethics Aspirin EC
39	COMPOUND ELECTROLYTES (new listing) Powder for oral soln – 1% DV Dec-16 to 20192.30	10	Enerlyte
CARI	DIOVASCULAR SYSTEM		
41	CILAZAPRIL (brand change)  Tab 2.5 mg – <b>1% DV Dec-16 to 2019</b>	200 200	Apo-Cilazapril Apo-Cilazapril
43	DISOPYRAMIDE PHOSPHATE (delisting) Cap 150 mg Note – Disopyramide phosphate cap 150 mg to be delisted from 1 April 201	7.	
DERI	MATOLOGICALS		
56	$\label{eq:hydrocorr} \begin{tabular}{ll} HYDROCORTISONE († price, addition of HSS and addition of DV Limit note) \\ Crm 1%, 500 g - 1% DV Dec-16 to 2019$	500 g	Pharmacy Health

Price (ex man, Excl. GST) \$

Brand or Generic Manufacturer

### Changes to Section H Part II - effective 1 October 2016 (continued)

#### **HORMONE PREPARATIONS**

63 CINACALCET

> 28 Sensipar

Restricted

Initiation

Nephrologist or endocrinologist

Re-assessment required after 6 months

Fither:

- 1 All of the following:
  - 1.1 The patient has been diagnosed with a parathyroid carcinoma (see Note); and
  - 1.2 The patient has persistent hypercalcaemia (serum calcium ≥ 3 mmol/L) despite previous first-line treatments including sodium thiosulfate (where appropriate) and bisphosphonates and sodium thiosulfate: and
  - 1.3 The patient is symptomatic; or
- 2 All of the following:
  - 2.1 The patient has been diagnosed with calciphylaxis (calcific uraemic arteriolopathy); and
  - 2.2 The patient has symptomatic (e.g. painful skin ulcers) hypercalcaemia (serum calcium ≥ 3 mmol/L); and
  - 2.3 The patient's condition has not responded to previous first-line treatments including bisphosphonates and sodium thiosulfate.

#### Continuation

Nephrologist or endocrinologist

Both:

- 1 The patient's serum calcium level has fallen to < 3mmol/L: and
- 2 The patient has experienced clinically significant symptom improvement.

Note: This does not include parathyroid adenomas unless these have become malignant.

67	GOSERELIN (amended presentation, ↓ price and addition of HSS)		
	Implant 3.6 mg, syringe – 1% DV Dec-16 to 2019	1	Zoladex
	Implant 10.8 mg, syringe – 1% DV Dec-16 to 2019177.50	1	Zoladex
67	LEUPRORELIN ACETATE (amended presentation description and brand nam	ie)	
	Inj 3.75 mg <b>prefilled dual chamber</b> syringe221.60	1	Lucrin Depot <del>PDS</del> <b>1-month</b>
	Inj 7.5 mg syringe <b>with diluent</b>	1	Eligard 1 Month
	Inj 11.25 mg <b>prefilled dual chamber</b> syringe591.68	1	Lucrin Depot <del>PDS</del> <b>3-month</b>
	Inj 22.5 mg syringe with diluent	1	Eligard 3 Month
	Inj 30 mg <b>prefilled dual chamber</b> syringe1,109.40	1	Lucrin Depot <del>PDS</del> <b>6-month</b>
	Inj 45 mg syringe <b>with diluent</b> 832.05	1	Eligard 6 month
INF	ECTIONS		
00	DOCEDDE//ID		

**BOCEPREVIR** 92

336 Victrelis Note - Victrelis cap 200 mg to be delisted from 1 April 2017.

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

Chan	ges to Section H Part II – effective 1 October 2016 (continued)	
NERV	OUS SYSTEM	
111	ASPIRIN (new listing)  Tab dispersible 300 mg – <b>1% DV Dec-16 to 2019</b>	Ethics Aspirin
126	FLUPHENAZINE DECANOATE Inj 25 mg per ml, 2 ml ampoule Note – Modecate inj 25 mg per ml, 2 ml ampoule to be delisted from 1 December 2016	e.g. Modecate
129	MIDAZOLAM (brand change) Inj 1 mg per ml, 5 ml ampoule – 1% DV Dec-16 to 20194.30 Inj 5 mg per ml, 3 ml ampoule – 1% DV Dec-16 to 20192.50 5 Note Hypnovel and Pfizer inj 1 mg per ml, 5 ml ampoule and 5 mg per ml, 3 ml ampules 1 December 2016.	Midazolam-Claris Midazolam-Claris to be delisted from
ONC	DLOGY AGENTS AND IMMUNOSUPPRESSANTS	
136	FLUDARABINE PHOSPHATE (addition of HSS) Inj 50 mg vial – 1% DV Dec-16 to 2019	Fludarabine Ebewe
RESP	PIRATORY SYSTEM AND ALLERGIES	
181	CETIRIZINE HYDROCHLORIDE (brand change)  Tab 10 mg – <b>1% DV Dec-16 to 2019</b>	Zista
181	IPRATROPIUM BROMIDE († price and addition of HSS)   Nebuliser soln 250 mcg per ml, 1 ml ampoule   - 1% DV Dec-16 to 2019	Univent Univent
183	SALBUTAMOL (delisting) Aerosol inhaler, 100 mcg per dose	Salamol
SENS	ORY ORGANS	
187	GANCICLOVIR (delisting) Eye gel 0.15% Note – Ganciclovir eye gel 0.15% to be delisted from 1 November 2016.	e.g. Virgan
EXTE	MPORANEOUSLY COMPOUNDED PREPARATIONS	
201	COAL TAR (new listing) Soln BP – <b>1% DV Dec-16 to 2019</b>	Midwest

201	COAL TAR (new listing)			
	Soln BP – 1% DV Dec-16 to 2019	5	200 ml	Midwest

Price	
(ex man. Excl. GST)	
\$	Per

Brand or Generic Manufacturer

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

## SPECIAL FOODS

217	ORAL FEED (new listing)  → Powder 16 g protein, 57.4 g carbohydrate and 14 g fat per 100 g, can		850 g 4).	Ensure (Chocolate)
217	ENTERAL FEED 1 KCAL/ML (delisting)  → Liquid 4 g protein, 14.1 g carbohydrate, 3.47 g fat and 1.76 g fibre per 100 ml, bottle	32 2	500 ml 237 ml June 2017.	Jevity RTH Jevity
217	ORAL FEED 1.5 KCAL/ML (delisting)  → Liquid 5.5 g protein, 21.1 g carbohydrate and 4.81 g fat per 100 ml, can		237 ml	Ensure Plus (Chocolate)
	Note - Ensure Plus (chocolate) liquid 237 ml to be delisted from 1 Ap	oril 2017.		

Price Brand or
(ex man. Excl. GST) Generic
\$ Per Manufacturer

## Changes to Section H Part II - effective 1 September 2016

#### **BLOOD AND BLOOD FORMING ORGANS**

30	IDARUCIZUMAB (new listing)  → Inj 50 mg per ml, 50 ml vial	2 situations o	Praxbind f life-threatening or
33	ENOXAPARIN <b>SODIUM</b> (chemical name change and ↓ price)		
	Inj 20 mg in 0.2 ml syringe30.91	10	Clexane
	Inj 40 mg in 0.4 ml syringe41.24	10	Clexane
	Inj 60 mg in 0.6 ml syringe62.18	10	Clexane
	Inj 80 mg in 0.8 ml syringe82.88	10	Clexane
	Inj 100 mg in 1 ml syringe103.80	10	Clexane
	Inj 120 mg in 0.8 ml syringe128.98	10	Clexane
	Inj 150 mg in 1 ml syringe147.41	10	Clexane
33	DABIGATRAN (1 price)		
	Cap 75 mg76.36	60	Pradaxa
	Cap 110 mg76.36	60	Pradaxa
	Cap 150 mg76.36	60	Pradaxa
36	PLERIXAFOR (new listing)		
	→ Inj 20 mg per ml, 1.2 ml vial	1	Mozobil

Initiation - autologous stem cell transplant

Haematologist

Limited to 3 days treatment

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 x 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 x  $10^{9}/L$  and a suboptimal peripheral blood CD34 count of  $\leq$ 10 x  $10^{9}/L$ ; 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) \$ Pe 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
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
37	GLUCOSE [DEXTROSE] (Pharmacode change) Inj 5%, bag  Note – Pharmacode change for 50 ml bag from 2232197 to 2076 466131.	3.87	50 ml 250 ml for 250 ml ba	Baxter Baxter g from 2076276 to
37	GLUCOSE [DEXTROSE] († price) Inj 10%, bag	9.33	500 ml 1,000 ml 500 ml	Baxter Baxter 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 CHLORID Inj 4% glucose with potassium chloride 20 mmol/l and sodium chloride 0.18%, bag	8.31	) 1,000 ml 1,000 ml	Baxter Baxter
37	GLUCOSE WITH SODIUM CHLORIDE († price) Inj glucose 2.5% with sodium chloride 0.45%, bag Inj glucose 5% with sodium chloride 0.9%, bag		500 ml 1,000 ml	Baxter Baxter
37	GLUCOSE WITH SODIUM CHLORIDE (delisting) Inj glucose 5% with sodium chloride 0.45%, bag Note – Baxter glucose with sodium chloride inj glucose 5% with sodiusted from 1 September 2016.		500 ml loride 0.45%, l	Baxter bag 500 ml to be
38	POTASSIUM CHLORIDE WITH SODIUM CHLORIDE († price) Inj 20 mmol/l potassium chloride with 0.9% sodium chloride, bag Inj 30 mmol/l potassium chloride with 0.9% sodium chloride, bag		1,000 ml	Baxter Baxter
38	POTASSIUM CHLORIDE WITH SODIUM CHLORIDE (Pharmacode Inj 40 mmol/l potassium chloride with 0.9% sodium chloride, bag		nd † price) 1,000 ml	Baxter

	(6		GST) Per	Brand or Generic Manufacturer
Cha	nges to Section H Part II – effective 1 Septen	nber 2016 (cont	tinued)	
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
CAR	DIOVASCULAR SYSTEM			
47	MANNITOL († price) Inj 10%, 1,000 ml bag Inj 20%, 500 ml bag		1,000 ml 500 ml	Baxter Baxter
47	MANNITOL (delisting) Inj 15%, 500 ml bag Note – Baxter mannitol inj 15%, 500 ml bag to be delist		500 ml per 2016.	Baxter
48	ATORVASTATIN (brand change)  Tab 10 mg – 1% Nov-16 to 2018  Tab 20 mg – 1% Nov-16 to 2018  Tab 40 mg – 1% Nov-16 to 2018  Tab 80 mg – 1% Nov-16 to 2018  Note – Zarator tab 10 mg, 20 mg, 40 mg and 80 mg to	13.32 21.23 36.26	500 500 500 500 500 November 20	Lorstat Lorstat Lorstat Lorstat 16.
DER	MATOLOGICALS			
54	MALATHION WITH PERMETHRIN AND PIPERONYL BU Spray 0.25% with permethrin 0.5% and piperonyl bu Note – Malathion with permethrin and piperonyl butoxic butoxide 2% to be delisted from 1 January 2017.	toxide 2%	n permethrin 0	.5% and piperonyl
56	CLOBETASOL PROPIONATE (brand change)  Crm 0.05% – <b>1% Dec-16 to 2019</b> Oint 0.05% – <b>1% Dec-16 to 2019</b> Note – Clobetasol BNM crm 0.05% and oint 0.05% to b	2.20	30 g 30 g December 201	Dermol Dermol 6.
GEN	ITO-URINARY SYSTEM			
59	CLOTRIMAZOLE (addition of HSS)  Vaginal crm 1% with applicator  – 1% Nov-16 to 2019 († price)  Vaginal crm 2% with applicator  – 1% Nov-16 to 2019 (↓ price)		35 g 20 g	Clomazol Clomazol
HOR	MONE PREPARATIONS			
64	ZOLEDRONIC ACID (new listing)  → Inj 4 mg per 5 ml, vial	84.50	1	Zoledronic acid Mylar

Price		Brand or
(ex man. Excl. GST)		Generic
 \$	Per	Manufacturer

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

## INFECTIONS

	, i i i i i i i i i i i i i i i i i i i		
74	CEFALEXIN (new listing) Cap 250 mg – 1% Dec-16 to 2019	20	Cephalexin ABM
74	CEFTRIAXONE (brand change) Inj 500 mg vial – <b>1% Nov-16 to 2019</b>	1 1 vember 2016.	DEVA DEVA
80	POSACONAZOLE (new listing)  → Tab modified-release 100 mg869.86	24	Noxafil
MUSC	CULOSKELETAL SYSTEM		
97	PYRIDOSTIGMINE BROMIDE († price and addition of HSS) Tab 60 mg – <b>1% Nov-16 to 2019</b>	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	5 5	Tracrium Tracrium
104	VECURONIUM BROMIDE (delisting) Inj 4 mg ampoule Note – Vecuronium bromide inj 4 mg ampule delisted from 1 September	2016.	
NERV	OUS SYSTEM		
108	DESFLURANE (‡ price and addition of HSS) Soln for inhalation 100%, 240 ml bottle - 1% Sep-16 to 20191,350.00	6	Suprane
108	ISOFLURANE (4 price and addition of HSS) Soln for inhalation 100%, 250 ml bottle - 1% Sep-16 to 2019	6	Aerrane
109	SEVOFLURANE (‡ price and addition of HSS) Soln for inhalation 100%, 250 ml bottle - 1% Sep-16 to 2019840.00	6	Baxter
123	AMISULPRIDE (brand change)  Tab 100 mg – <b>1% Nov-16 to 2019</b>	30 60 60 mber 2016.	Sulprix Sulprix Sulprix
124	CHLORPROMAZINE HYDROCHLORIDE (new listing) Oral liq 20 mg per ml		

Price		Brand or
(ex man. Excl. GST)		Generic
\$	Per	Manufacturer

## 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 Disposed at Oscial database and dispose ible O. F. man. 4 ma			luna 0017

Note – Risperdal Quicklet tab orodispersible 0.5 mg, 1 mg and 2 mg to be delisted from 1 June 2017.

#### 133 NICOTINE (discontinuation)

Gum	ո 2 mg –	1% DV Apr-14 to 2017	22.26	384	Habitrol (Classic)
Gun	n 4 mg –	1% DV Apr-14 to 2017	25.67	384	Habitrol (Classic)
o+o	Habitral	(Classia) aum 0 ma ana	1 1 mg to be delicted from 1 March	2017 Hobite	laum 0 ma and 1 me

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 eyeles of **5 days treatment**, at a maximum dose of 200 mg/m² **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/m² 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

Price		Brand or
(ex man. Excl. GST)		Generic
\$	Per	Manufacturer

## 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 (1 price)

Inj 100 mg per ml,	4 ml ampoule – <b>1% DV Oct-16 to 2019</b> 161.25	15	Uromitexan
Inj 100 mg per ml,	10 ml ampoule – 1% DV Oct-16 to 2019370.35	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 2	017.	

178 NIVOLUMAB (amended restriction)

<b>→</b>	· Inj 10 mg per ml, 4 ml vial	1,051.98	1	Opdivo
<b>→</b>	· Inj 10 mg per ml, 10 ml vial	2,629.96	1	Opdivo

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 Fither
  - 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 cvcles); 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

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
- 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:

 $\hbox{ Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) } \\$ 

Price		Brand or
(ex man. Excl. (	GST)	Generic
\$	Per	Manufacturer

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

continued

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)

Kevtruda

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
- - 3.1 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

Price	
(ex man. Excl. GST)	
\$	Per

Brand or Generic Manufacturer

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

continued...

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.</li>
- 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	100 ml 100 ml 500 ml	Baxter Baxter Baxter
	Irrigation soln 0.1%, bottle8.71	100 ml	Baxter
199	CHLORHEXIDINE (delisting) Irrigation soln 0.5%, bottle	500 ml from 1 Septe	Baxter mber 2016.
199	CHLORHEXIDINE WITH CETRIMIDE († price) Irrigation soln 0.015% with cetrimide 0.15%, bottle	100 ml 500 ml 500 ml 100 ml	Baxter Baxter Baxter Baxter
199	CHLORHEXIDINE WITH CETRIMIDE (Pharmacode change and † price) Irrigation soln 0.05% with cetrimide 0.5%, bottle9.31 Note – Pharmacode change from 2076152 to 2084430.	100 ml	Baxter
199	CHLORHEXIDINE WITH CETRIMIDE (delisting) Irrigation soln 0.1% with cetrimide 1%, bottle	500 ml e 1%, bottle 50	Baxter 00 ml to be delisted

		Price (ex man. Excl. \$	GST) Per	Brand or Generic Manufacturer
Char	nges to Section H Part II – effective 1 Septem	per 2016 (con	tinued)	
99	GLYCINE († price) Irrigation soln 1.5%, bottle	19.48 22.70	2,000 ml 3,000 ml	Baxter Baxter
99	SODIUM CHLORIDE († price) Irrigation soln 0.9%, bottle	5.22 6.19 6.59 19.26	100 ml 500 ml 1,000 ml 3,000 ml	Baxter Baxter Baxter Baxter
99	SODIUM CHLORIDE (Pharmacode change and † price) Irrigation soln 0.9%, bottle Note – Pharmacode change from 785091 to 307122.	15.11	2,000 ml	Baxter
99	WATER († price) Irrigation soln, bottle	5.24 5.94 6.58	100 ml 500 ml 1,000 ml	Baxter Baxter Baxter

#### **SPECIAL FOODS**

2089963.

199

212 AMINO ACID FORMULA

Note - Pharmacode change for 2.000 ml bag from 2076799 to 761958, and for 3.000 ml bag from 2076780 to

#### **PART I – GENERAL RULES**

7 HOSPITAL SUPPLY OF PHARMACEUTICALS

WATER (Pharmacode change and † price)

- 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:
    - a) Medical Devices;
    - b) whole or fractionated blood products;
    - c) diagnostic products which have an ex vivo use, such as pregnancy tests and reagents;
    - d) disinfectants and sterilising products, except those that are to be used in or on a patient;
    - e) foods and probiotics;
    - f) radioactive materials;
    - g) medical gases; and
    - h) parenteral nutrition; and
    - i) pharmaceutical products for in-vivo investigation of allergy.

Subject to rule 2.2, the funding of pharmaceuticals identified in a)—i) h) above is a decision for individual DHB Hospitals.

2.000 ml

3.000 ml

29.21

Baxter

Baxter

Price		Brand or
(ex man. Excl. GST)		Generic
\$	Per	Manufacturer

## Changes to Section H Part II – effective 1 August 2016

ALIMENTARY	TRACT AND	METABOLISM
ALIWENIAKT	IKAGI AND	INELABULISIN

ALIIVI	ENTARY TRACT AND METABULISM			
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  Tab EC 500 mg – 1% DV Oct-16 to 2019		100 100	Salazopyrin 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 n Cap 1.25 mg (50,000 iu)		12	Vit.D3
BLOO	D AND BLOOD FORMING ORGANS			
38	SODIUM CHLORIDE (amended presentation description, † prior Inj 23.4% (4 mmol/ml), 20 ml ampoule  - 1% DV Oct-16 to 2019		on of HSS) 5	Biomed
CARE	DIOVASCULAR SYSTEM			
43	AMIODARONE HYDROCHLORIDE (new listing)  Tab 100 mg – 1% <b>DV Oct-16 to 2019</b> Tab 200 mg – 1% <b>DV Oct-16 to 2019</b>		30 30	Cordarone X Cordarone X
44	LABETALOL († price) Tab 50 mg Tab 100 mg Tab 200 mg	11.36	100 100 100	Hybloc Hybloc Hybloc
44	METOPROLOL SUCCINATE (HSS delayed)  Tab long-acting 23.75 mg — 1% DV Nov-16 Jan-17 to 2018  Tab long-acting 47.5 mg — 1% DV Nov-16 Jan-17 to 2018  Tab long-acting 95 mg — 1% DV Nov-16 Jan-17 to 2018  Tab long-acting 190 mg — 1% DV Nov-16 Jan-17 to 2018	3.48 5.73	90 90 90 90	Metoprolol - AFT CR Metoprolol - AFT CR Metoprolol - AFT CR Metoprolol - AFT CR
45	SOTALOL († price and addition of HSS)  Tab 80 mg – <b>1% DV Oct-16 to 2019</b> Tab 160 mg – <b>1% DV Oct-16 to 2019</b>		500 100	Mylan 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 – <b>1% DV Oct-16 to 2019</b> († price)  Tab 100 mg – <b>1% DV Oct-16 to 2019</b>		100 100	Spiractin Spiractin

		Price		Brand or
	(ex mar	n. Excl. GST \$	) Per	Generic Manufacturer
Cha	nges to Section H Part II – effective 1 August 2016 (co	ontinued)		
49	ISOSORBIDE MONONITRATE († price) Tab long-acting 60 mg	. 8.49	90	Duride
DER	MATOLOGICALS			
54	PHENOTHRIN (new listing) Shampoo 0.5%			
GEN	ITO-URINARY SYSTEM			
60	LEVONORGESTREL (new listing)  → Intra-uterine system, 20 mcg per day  – 1% DV Aug-16 to 2019	69.50	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		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 < 2.2 The patient has a history of pre-term birth at less than 28 w		3 to 28 wee	eks); or
	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; a 3. Either: 3.1. The patient has a short cervix on ultrasound (defined as 3.2. The patient has a history of pre-term birth at less than 2	< 25 mm a	t 16 to 28	weeks); or
	Note: Indications marked with * are Unapproved Indications (refer (Interpretations and Definitions) and Part IV (Miscellaneous Provisi			Rules, Part I
HOR	MONE 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 14.00	30 100 30	Provera Provera Provera

		Price	10T)	Brand or
	(	ex man. Excl. G \$	iST) Per	Generic Manufacturer
Char	nges to Section H Part II – effective 1 August 20	16 (continued	l)	
65	OESTRADIOL (new listing) Patch 25 mcg per day – 1% DV Oct-16 to 2019 Patch 50 mcg per day – 1% DV Oct-16 to 2019 Patch 100 mcg per day – 1% DV Oct-16 to 2019	7.04	8 8 8	Estradot Estradot Estradot
66	MEDROXYPROGESTERONE († price, addition of HSS and at Tab 100 mg – 1% DV Oct-16 to 2019	mended brand i	name) 100	Provera HD Provera
INFE	CTIONS			
74	CEFALEXIN (4 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% <b>DV Oct-16 to 2019</b>	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
MUS	CULOSKELETAL SYSTEM			
97	PENICILLAMINE († price) Tab 125 mg Tab 250 mg		100 100	D-Penamine D-Penamine
98	ALENDRONATE SODIUM WITH <b>COLECALCIFEROL</b> CHOLEC description amendment)	<del>ALCIFEROL</del> (cl	nemical name	e and presentation
	→ Tab 70 mg with <b>colecalciferol</b> <del>cholecalciferol</del> 5,600 iu	12.90	4	Fosamax Plus
NER	VOUS SYSTEM			
113	MORPHINE TARTRATE († price, addition of HSS and amend Inj 80 mg per ml, 1.5 ml ampoule – 1% DV Oct-16 to 20		e) 5	DBL Morphine Tartrate Hospira
115	DOTHIEPIN HYDROCHLORIDE († price) Tab 75 mg Cap 25 mg		100 100	Dopress Dopress
116	FLUOXETINE HYDROCHLORIDE (addition of HSS)  Tab dispersible 20 mg, scored  - 1% DV Oct-16 to 2019 (‡ price)		30 90	Arrow-Fluoxetine Arrow-Fluoxetine

		Price	CT)	Brand or
		(ex man. Excl. 6 \$	Per	Generic Manufacturer
Chai	nges to Section H Part II – effective 1 August	2016 (continued	d)	
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 Ondanaccord inj 2 mg per ml, 4 ml ampoule will also be	will now begin fro		
124	HALOPERIDOL (addition of HSS)  Tab 500 mcg – 1% DV Oct-16 to 2019  Tab 1.5 mg – 1% DV Oct-16 to 2019  Tab 5 mg – 1% DV Oct-16 to 2019  Oral liq 2 mg per ml – 1% DV Oct-16 to 2019  Inj 5 mg per ml, 1ml ampoule – 1% DV Oct-16 to 2019	9.43 29.72 23.84	100 100 100 100 ml 10	Serenace Serenace Serenace Serenace Serenace
ONC	OLOGY 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 Inj 25 mg per ml, 2 ml vial – 1% DV Oct-16 to 2019		5	DBL Methotrexate
	Inj 25 mg per ml, 20 ml vial – 1% DV Oct-16 to 2019	45.00	1	Onco-Vial <del>Hospira</del> DBL Methotrexate Onco-Vial <del>Hospira</del>
137	DACARBAZINE († price, addition of HSS and amended b Inj 200 mg vial – 1% DV Oct-16 to 2019		1	DBL Dacarbazine Hospira
138	TEMOZOLOMIDE (amended restriction)  Cap 5 mg			Temaccord Temaccord Temaccord Temaccord
		antly with radiother		ycles of 5 days

Re-assessment required after 9 months

All of the following:

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

Price (ex man, Excl. GST) \$

Brand or Generic Manufacturer

## Changes to Section H Part II - effective 1 August 2016 (continued)

144

- continued...
  3. Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a
  - 4. Temozolomide to be discontinued at disease progression.

Continuation - Neuroendocrine tumours

Re-assessment required after 6 months

MESNA († price and addition of HSS)

- 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 itsbenefit 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	Tab 400 mg – 1% <b>DV Oct-16 to 2019</b>	50 50 15 15	Uromitexan Uromitexan Uromitexan Uromitexan
144	VINCRISTINE SULPHATE († price, addition of HSS and amended brand na Inj 1 mg per ml, 1 ml vial – 1% DV Oct-16 to 201974.52	ame) 5	DBL Vincristine Sulfate Hospira
	Inj 1 mg per ml, 2 ml vial – 1% <b>DV Oct-16 to 2019</b> 85.61	5	DBL Vincristine Sulfate Hospira
RESP	IRATORY SYSTEM AND ALLERGIES		
180	BECLOMETHASONE DIPROPIONATE († price) Nasal spray 50 mcg per dose	200 dose 200 dose	Alanase Alanase
181	BUDESONIDE († price) Nasal spray 50 mcg per dose	200 dose 200 dose	Butacort Aqueous Butacort Aqueous
181	PROMETHAZINE HYDROCHLORIDE († price and addition of HSS) Inj 25 mg per ml, 2 ml ampoule – 1% DV Oct-16 to 201915.54	5	Hospira
SENS	ORY ORGANS		
187	ACICLOVIR (new listing) Eye oint 3% – 1% DV Oct-16 to 201914.92	4.5 g	ViruPOS
SPEC	IAL 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	178 ml	Impact Advanced Recovery

Price		Brand or
(ex man. Excl. GST)		Generic
\$	Per	Manufacturer

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

216 HIGH ARGININE ORAL FEED 1.4 KG
------------------------------------

→ 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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## Pharmaceuticals and brands

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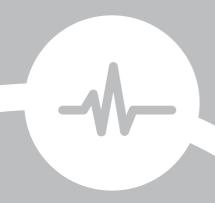
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#### New Zealand Government

New Zealand Permit No. 478





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