Pharmaceutical Management Agency New Zealand Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

June 2025



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Summary of decisions EFFECTIVE 1 JUNE 2025

- Ambrisentan (Ambrisentan Viatris) tab 5 mg and 10 mg amended restriction criteria
- Aripiprazole (Abilify Maintena) inj 300 mg vial and 400 mg vial
 - Pharmacodes 2670976 and 2670984 delisted 1 June 2025
- Atovaquone with proguanil hydrochloride tab 62.5 mg with proguanil hydrochloride 25 mg (Malarone Junior) and tab 250 mg with proguanil hydrochloride (Malarone) – price increase
- Chlorhexidine with cetrimide (LumaCina) irrigation soln 0.015% with cetrimide 0.15%, 30 ml ampoule new listing and addition of PSS
- Chlorhexidine with cetrimide (Pfizer) irrigation soln 0.015% with cetrimide 0.15%,
 30 ml ampoule to be delisted from 1 September 2025
- Ciprofloxacin (Ciprofloxacin Kabi) inj 2 mg per ml, 100 ml bottle price increase
- Dabrafenib (Tafinlar) cap 50 mg and 75 mg new listing
- Dexmedetomidine (Dexmedetomidine Viatris) inj 100 mcg per ml, 2 ml vial
 new Pharmacode listing
- Enteral feed 1.2 kcal/ml (Jevity Plus RTH) liquid 5.55 g protein, 15.1 g carbohydrate, 3.93 g fat and 2 g fibre per 100 ml, 1,000 ml bottle – to be delisted 1 September 2025
- Ethosuximide (Zarontin) cap 250 mg new Pharmacode listing
- Ethosuximide (Zarontin) cap 250 mg Pharmacode 2489937 delisted 1 June 2025
- Famotidine (Famotidine Hovid MY) tab 40 mg new listing
- Fludarabine phosphate (Fludarabine Sagent) inj 50 mg vial to be delisted
 1 November 2025
- Gentamicin sulphate (Gentamicin Hikma) inj 10 mg per ml, 2 ml ampoule
 delisted 1 June 2025
- Haemophilus influenzae type B vaccine (Act-HIB) inj 10 mcg vial with diluent syringe
 new Pharmacode listing
- Infliximab (Remicade) inj 100 mg vial amended restriction criteria
- Ipratropium bromide (Accord) nebuliser soln 250 mcg per ml, 2 ml ampoule
 new listing
- Itraconazole (Itracap) cap 100 mg to be delisted 1 December 2025
- Lithium carbonate (Douglas) cap 250 mg price increase
- Low electrolyte oral feed 1.8 kcal/ml (Nepro HP (strawberry) and Nepro HP (vanilla)) liquid 8 g protein, 14.74 g carbohydrate, 9.77 g fat and 1.26 g fibre per 100 ml, 220 ml bottle amended prescription description
- Nivolumab (Opdivo) inj 10 mg per ml, 4 ml vial and 10 ml vial

 amended restriction criteria

Summary of decisions – effective 1 June 2025 (continued)

- Pembrolizumab (Keytruda) inj 25 mg per ml, 4 ml vial amended restriction criteria
- Phenytoin sodium (Hospira) inj 50 mg per ml, 2 ml ampoule to be delisted 1 February 2026
- Phytomenadione (Konakion MM Paediatric) inj 2 mg in 0.2 ml ampoule
 amended brand name
- Propranolol (e.g. Hikma-Propranolol) oral liq 4 mg per ml listing of an example brand
- Sotalol (Sotalol Viatris) tab 80 mg new listing
- Tocilizumab (Actemra) inj 20 mg per ml, 4 ml vial, 10 ml vial and 20 ml vial
 amended restriction criteria
- Trametinib (Mekinist) tab 0.5 mg and 2 mg new listing
- Zoledronic acid (Zoledronic acid Viatris) inj 4 mg per 5 ml, vial new Pharmacode listing

Brand or Generic Manufacturer

Section H changes to Part II

Effective 1 June 2025

ALIMENTARY TRACT AND METABOLISM

EAMOTIDINE (new licting)

CARD	DIOVASCULAR SYSTEM			
34	PHYTOMENADIONE (amended brand name) Inj 2 mg in 0.2 ml ampoule	8.00	5	Konakion MM Paediatric
BLOO	D AND BLOOD FORMING ORGANS			
U	Tab 40 mg	10.27	100	Famotidine Hovid MY

47	PROPRANOLOL (listing of an example brand)
	Oral liq 4 mg per ml

e.g. Hikma- Propranolol

47 SOTALOL (new listing)

300

Sotalol Viatris

54 AMBRISENTAN (amended restriction criteria – affected criteria shown only)

30 Ambrisentan Viatris 30 Amhrisentan Viatris

Restricted

Initiation – PAH dual therapy

Respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist

Limited to 6 months treatment

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5}): and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these quidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both All of the following:

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

Brand or Generic

Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

continued...

- 5.1 Ambrisentan is to be used as PAH dual therapy; and
- 5.2 Either:
 - 5.2.1 Patient has tried a PAH monotherapy (sildenafil or bosentan) for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool**: or
 - 5.2.2 Patient has tried PAH dual therapy including bosentan and has experienced intolerable side effects on bosentan: and
- 5.3 Both:
 - 5.3.1 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would benefit from initial dual therapy; and
 - 5.3.2 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease).
- 5.2 Any of the following:
 - 5.2.1 Patient has tried bosentan (either as PAH monotherapy, or PAH dual therapy with sildenafil) for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool**: or
 - 5.2.2 Patient has experienced intolerable side effects on bosentan; or
 - 5.2.3 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
 - 5.2.4 Patient is presenting in NYHA/WHO functional class III or IV, and would benefit from initial dual therapy in the opinion of the treating clinician and has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease).

HORMONE PREPARATIONS

78	ZOLEDRONIC ACID (new Pharmacode listing)		
	Inj 4 mg per 5 ml, vial – 5% DV Dec-24 to 2027	1	Zoledronic acid Viatris
	Note – this is a new Pharmacode listing 2706032.		

INFECTIONS

87	GENTAMICIN SULPHATE (delisted) Inj 10 mg per ml, 2 ml ampoule Note – Gentamicin Hikma inj 10 mg per ml, 2 ml ampoule (bran		10 ed 1 June	Gentamicin Hikma 2025.
92	CIPROFLOXACIN († price) → Inj 2 mg per ml, 100 ml bottle	. 166.50	10	Ciprofloxacin Kabi
96	ITRACONAZOLE (delisting) → Cap 100 mg Note – Itracap cap 100 mg to be delisted from 1 December 202		60	Itracap
101	ATOVAQUONE WITH PROGUANIL HYDROCHLORIDE († price) → Tab 62.5 mg with proguanil hydrochloride 25 mg → Tab 250 mg with proguanil hydrochloride 100 mg		12 12	Malarone Junior Malarone
NEDVOIIC CYCTEM				

NERVOUS SYSTEM

120	DEXMEDETOMIDINE (new Pharmacode listing)		
	Inj 100 mcg per ml, 2 ml vial – 5% DV May-24 to 2026 42.00	5	Dexmedetomidine Viatris
	Note – this is a new Pharmacode listing 2696258		

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

Changes to Section H Part II – effective 1 June 2025 (continued)

128	PHENYTOIN SODIUM (delisting) Inj 50 mg per ml, 2 ml ampoule Note – Hospira inj 50 mg per ml, 2 ml ampoule to be delisted fr			Hospira
128	ETHOSUXIMIDE (new Pharmacode listing) Cap 250 mg Note – this listing is for Pharmacode 2705117.	.140.88	100	Zarontin
128	ETHOSUXIMIDE (delisted) Cap 250 mg Note – this delist applies to Pharamcode 2489937 from 1 June		100	Zarontin
133	LITHIUM CARBONATE († price) Cap 250 mg	35.78	100	Douglas
134	ARIPIPRAZOLE (delisted) → Inj 300 mg vial → Inj 400 mg vial Note – this delist only applies to Pharmacodes 2670976 and 26	.341.96	1	Abilify Maintena Abilify Maintena n 1 June 2025.

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

149	FLUDARABINE PHOSPHATE (delisting)
	Inj 50 mg vial

158 DABRAFENIB (new listing)

→ Cap 50 mg	6,320.86	120	Tafinlar
→ Cap 75 mg	9,481.29	120	Tafinlar

Restricted

Initiation - stage III or IV resected melanoma - adjuvant

Any relevant practitioner

Reassessment required after 4 months

Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a); or
 - 2.1.2 Both:
 - 2.1.2.1 The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor; and
 - 2.1.2.2 Adjuvant treatment with dabrafenib is required; and
 - 2.2 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma: and
 - 2.3 Treatment must be adjuvant to complete surgical resection; and
 - 2.4 Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and
 - 2.5 The individual has a confirmed BRAF mutation; and
 - 2.6 Dabrafenib must be administered in combination with trametinib; and
 - 2.7 The individual has ECOG performance score 0-2.

Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

Notes:

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- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

Continuation - stage III or IV resected melanoma - adjuvant

Any relevant practitioner

Reassessment required after 4 months

All of the following:

- 1 No evidence of disease recurrence: and
- 2 Dabrafenib must be administered in combination with trametinib; and
- 3 Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadjuvant treatment.

Initiation - unresectable or metastatic melanoma

Any relevant practitioner

Reassessment required after 4 months

Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
 - 2.2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
 - 2.3 The individual has ECOG performance score 0-2: and
 - 2.4 The individual has confirmed BRAF mutation; and
 - 2.5 Dabrafenib must be administered in combination with trametinib; and
 - 2.6 Any of the following:
 - 2.6.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
 - 2.6.2 The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor; or
 - 2.6.3 All of the following:
 - 2.6.3.1 The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor; and
 - 2.6.3.2 The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor; and
 - 2.6.3.3 The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor.

Continuation – unresectable or metastatic melanoma

Any relevant practitioner

Reassessment required after 4 months

Both:

- 1 Any of the following:
 - 1.1 The individual's disease has had a complete response to treatment; or
 - 1.2 The individual's disease has had a partial response to treatment; or
 - 1.3 The individual has stable disease with treatment: and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.

Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

165 TRAMETINIB (new listing)

→ Tab 0.5 mg.......2,370.32 Mekinist 30 Mekinist

Restricted

Initiation - stage III or IV resected melanoma - adjuvant

Any relevant practitioner

Reassessment required after 4 months

Fither:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment: or
- 2 All of the following:
 - 2.1 Fither:
 - 2.1.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a); or
 - 2.1.2 Both:
 - 2.1.2.1 The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor; and
 - 2.1.2.2 Adjuvant treatment with trametinib is required; and
 - 2.2 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma: and
 - 2.3 Treatment must be adjuvant to complete surgical resection; and
 - 2.4 Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and
 - 2.5 The individual has a confirmed BRAF mutation; and
 - 2.6 Trametinib must be administered in combination with dabrafenib; and
 - 2.7 The individual has ECOG performance score 0-2.

Notes:

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

Continuation - stage III or IV resected melanoma - adjuvant

Any relevant practitioner

Reassessment required after 4 months

All of the following:

- 1 No evidence of disease recurrence: and
- 2 Trametinib must be administered in combination with dabrafenib; and
- 3 Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadiuvant treatment.

Initiation - unresectable or metastatic melanoma

Any relevant practitioner

Reassessment required after 4 months

Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 The individual has metastatic or unresectable melanoma (excluding uyeal) stage III or IV: and
 - 2.2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
 - 2.3 The individual has ECOG performance score 0-2: and
 - 2.4 The individual has confirmed BRAF mutation: and
 - 2.5 Trametinib must be administered in combination with dabrafenib: and
 - 2.6 Any of the following:
 - 2.6.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
 - 2.6.2 The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor; or

Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

continued...

- 2.6.3 All of the following:
 - 2.6.3.1 The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor; and
 - 2.6.3.2 The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor: and
 - 2.6.3.3 The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor.

Continuation – unresectable or metastatic melanoma

Any relevant practitioner

Reassessment required after 4 months

Both:

- 1 Any of the following:
 - 1.1 The individual's disease has had a complete response to treatment; or
 - 1.2 The individual's disease has had a partial response to treatment; or
 - 1.3 The individual has stable disease with treatment; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.
- 200 INFLIXIMAB (amended restriction criteria – new criteria shown only)

Remicade

Restricted

Initiation – immune checkpoint inhibitor toxicity in malignancy*

Any relevant practitioner

Reassessment required after 4 months

All of the following:

- 1 The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy; and
- 2 The individual has received insufficient benefit from use of corticosteroids; and
- 3 Infliximab is to be administered at up to 5 mg/kg for up to four doses.

Continuation – immune checkpoint inhibitor toxicity in malignancy*

Any relevant practitioner

Reassessment required after 4 months

Roth:

- 1 The individual has shown clinical improvement and ongoing treatment is required; and
- 2 Infliximab is to be administered at up to 5 mg/kg for up to a total of 8 doses.

Note: Indications marked with * are unapproved indications.

TOCIL IZUMAB (amended restriction criteria – new criteria shown only) 230

→ Inj 20 mg per ml, 4 ml vial	220.00	1	Actemra
→ Inj 20 mg per ml, 10 ml vial	550.00	1	Actemra
→ Ini 20 mg per ml. 20 ml vial	1.100.00	1	Actemra

Restricted

Initiation – immune checkpoint inhibitor toxicity in malignancy*

Any relevant practitioner

Reassessment required after 4 months

All of the following:

- 1 The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy; and
- 2 The individual has received insufficient benefit from use of corticosteroids; and
- 3 Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly.

Continuation – immune checkpoint inhibitor toxicity in malignancy*

Any relevant practitioner

Generic

Brand or Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

continued...

Reassessment required after 4 months

Both:

- 1 The individual has shown clinical improvement and ongoing treatment is required; and
- 2 Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly.

Note: Indications marked with * are unapproved indications.

- NIVOLUMAB (amended restriction criteria affected criteria shown only) 242
 - Opdivo 1 Opdivo

Restricted

Initiation – unresectable or metastatic melanoma

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist Medical Oncologist Limited to 4 months treatment

All of the following:

- 1 The individual Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The individual patient has ECOG performance 0-2; and
- 4 Either:
 - 4.1 The individual Patient has not received funded pembrolizumab; or
 - 4.2 Both:
 - 4.2.1 The individual Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
 - 4.2.2 The cancer did not progress while **individual** patient was on pembrolizumab; and
- 5 Any of the following: Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses
 - 5.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
 - 5.2 The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; or
 - 5.3 All of the following:
 - 5.3.1 The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; and
 - 5.3.2 The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor: and
 - 5.3.3 The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor.

Continuation – unresectable or metastatic melanoma, less than 24 months on treatment

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist Medical oncologist. Reassessment required after 4 months

Fither:

- 1 Both All of the following:
 - 1.1 Any of the following:
 - 1.1.1 **The individual's** Patient's disease has had a complete response to treatment: or
 - 1.1.2 The individual's Patient's disease has had a partial response to treatment; or
 - 1.1.3 The individual Patient has stable disease: and
 - 1.2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; or and
 - 1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
- 2 All of the following:
 - 2.1 The individual Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
 - 2.2 The individual Patient has signs of disease progression; and
 - 2.3 Disease has not progressed during previous treatment with nivolumab

Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

continued...

Continuation – unresectable or metastatic melanoma, more than 24 months on treatment

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist Medical oncologist. Reassessment required after 4 months

- 1 The individual Patient has been on treatment for more than 24 months; and
- 2 Either:
 - 2.1 Both All of the following:
 - 2.1.1 Any of the following:
 - 2.1.1.1 The individual's Patient's disease has had a complete response to treatment; or
 - 2.1.1.2 The individual's Patient's disease has had a partial response to treatment; or
 - 2.1.1.3 The individual Patient has stable disease; and
 - 2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; or and
 - 2.1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
 - 2.2 All of the following:
 - 2.2.1 The individual Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
 - 2.2.2 The individual Patient has signs of disease progression; and
 - 2.2.3 Disease has not progressed during previous treatment with nivolumab.
- PEMBROLIZUMAB (amended restriction criteria affected criteria shown only) 244
 - Keytruda

Restricted

Initiation – stage III or IV resectable melanoma - neoadiuvant

Relevant specialist or from any relevant practitioner on the recommendation of a relevant specialist Limited to 4 months treatment

Either:

- 1 The individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uyeal) (see note); and
 - 2.2 The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB. IIIC. IIID or IV melanoma: and
 - 2.3 Treatment must be prior to complete surgical resection; and
 - 2.4 Pembrolizumab must be administered as monotherapy; and
 - 2.5 The individual has ECOG performance 0-2; and
 - 2.6 Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent).

Note: Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

Initiation - stage III or IV resected melanoma - adjuvant

Relevant specialist or from any relevant practitioner on the recommendation of a relevant specialist Reassessment required after 4 months

Either:

- 1 The individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment: or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uyeal) (see note a); or
 - 2.1.2 Both:
 - 2.1.2.1 The individual has received neoadiuvant treatment with pembrolizumab; and
 - 2.1.2.2 Adjuvant treatment with pembrolizumab is required; and

Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

- 2.2 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma: and
- 2.3 Treatment must be in addition to complete surgical resection; and
- 2.4 Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and
- 2.5 Pembrolizumab must be administered as monotherapy; and
- 2.6 The individual has ECOG performance 0-2; and
- 2.7 Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent).

Notes:

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means either 13 weeks after resection (primary or lymphadenectomy) or 13 weeks prior to the scheduled date of the resection (primary or lymphadenectomy)

Continuation - stage III or IV resected melanoma - adjuvant

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist

Reassessment required after 4 months

All of the following:

- 1 No evidence of disease recurrence: and
- 2 Pembrolizumab must be administered as monotherapy; and
- 3 Pembrolizumab to be administered at a fixed dose of 200 mg every three weeks (or equivalent) for a maximum of 12 months total treatment course, including any systemic negativeant treatment; and
- 4 Treatment to be discontinued at signs of disease recurrence or at completion of 12 months total treatment course (equivalent to 18 cycles at a dose of 200 mg every 3 weeks), including any systemic neoadjuvant treatment.

Initiation - unresectable or metastatic melanoma

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist Medical Oncologist Limited to 4 months treatment

All of the following:

- 1 The individual Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The individual Patient has ECOG performance 0-2; and
- 4 Either:
 - 4.1 The individual Patient has not received funded nivolumab; or
 - 4.2 Both:
 - 4.2.1 The individual Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
 - 4.2.2 The cancer did not progress while the **individual** patient was on nivolumab; and
- 5 Any of the following: Documentation confirming that the patient has been informed and acknowledges that fundedtreatment with pembrolizumab will not be continued if their disease progresses
 - 5.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
 - 5.2 The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; or
 - 5.3 All of the following:
 - 5.3.1 The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; and
 - 5.3.2 The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor; and
 - 5.3.3 The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor.

Continuation - unresectable or metastatic melanoma, less than 24 months on treatment

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist Medical oncologist. Reassessment required after 4 months

Fither:

- 1 Both All of the following:
 - 1.1 Any of the following:

Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

- 1.1.1 The individual's Patient's disease has had a complete response to treatment; or
- 1.1.2 The individual's Patient's disease has had a partial response to treatment; or
- 1.1.3 The individual Patient has stable disease; and
- 1.2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; or and
- 1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
- 2 All of the following:
 - 2.1 **The individual Patient** has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
 - 2.2 The individual Patient has signs of disease progression; and
 - 2.3 Disease has not progressed during previous treatment with pembrolizumab

Continuation – unresectable or metastatic melanoma, more than 24 months on treatment

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist Medical oncologist. Reassessment required after 4 months

Both:

- 1 The individual Patient has been on treatment for more than 24 months; and
- 2 Either:
 - 2.1 All of the following:
 - 2.1.1 Any of the following:
 - 2.1.1.1 The individual's Patient's disease has had a complete response to treatment; or
 - 2.1.1.2 The individual's Patient's disease has had a partial response to treatment; or
 - 2.1.1.3 The individual Patient has stable disease; and
 - 2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; and
 - 2.1.3 The treatment remains clinically appropriate and the **individual** patient is benefitting from the treatment; or
 2.2 All of the following:
 - 2.2.1 **The individual** Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
 - 2.2.2 The individual Patient has signs of disease progression; and
 - 2.2.3 Disease has not progressed during previous treatment with pembrolizumab.

Initiation - MSI-H/dMMR advanced colorectal cancer

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist

Re-assessment required after 4 months

Either:

- 1 Individual Patient is currently on treatment with pembrolizumab and met all remaining criteria before starting treatment; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Individual Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer: or
 - 2.1.2 Individual Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer; and
 - 2.2 Individual Patient is treated with palliative intent: and
 - 2.3 Individual Patient has not previously received funded treatment with pembrolizumab for MSI-H/dMMR advanced colorectal cancer; and
 - 2.4 Individual Patient has an ECOG performance score of 0-2; and
 - 2.5 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
 - 2.6 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

Initiation – relapsed/refractory Hodgkin lymphoma

Relevant specialist or any relevant practitioner on the recommendation of a relevant specialist

Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 June 2025 (continued)

continued...

Re-assessment required after 4 months

- 1 **Individual** Patient is currently on treatment with pembrolizumab and met all remaining criteria before starting treatment;
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Both:
 - 2.1.1.1 Individual Patient has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy: and
 - 2.1.1.2 Individual Patient is ineligible for autologous stem cell transplant; or
 - 2.1.2 Individual Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant; and
 - 2.2 Individual Patient has not previously received funded pembrolizumab for relapsed/refractory Hodgkin lymphoma;
 - 2.3 Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks.

RESPIRATORY SYSTEM AND ALLERGIES

257 IPRATROPIUM BROMIDE (new listing) Nebuliser soln 250 mcg per ml, 2 ml ampoule......11.73 20 Accord

VARIOUS

278 CHLORHEXIDINE WITH CETRIMIDE (new listing and addition of PSS)

Irrigation soln 0.015% with cetrimide 0.15%,

LumaCina 30

Note – Pfizer irrigation soln 0.015% with cetrimide 0.15%, 30 ml ampoule to be delisted from 1 September 2025.

SPECIAL FOODS

298 LOW ELECTROLYTE ORAL FEED 1.8 KCAL/ML (amended presentation description)

Liquid 8 g protein, 14,74 g carbohydrate, 9,77 g fat and

1 Nepro HP (strawberry) Nepro HP (vanilla)

300 ENTERAL FEED 1.2 KCAL/ML (delisting)

→ Liquid 5.55 g protein, 15.1 g carbohydrate, 3.93 g fat and 2 g fibre per

Jevity Plus RTH

Note – Jevity Plus RTH liquid 5.55 g protein, 15.1 g carbohydrate, 3.93 g fat and 2 g fibre per 100 ml, 1,000 ml bottle to be delisted from 1 September 2025.

VACCINES

303 HAEMOPHILUS INFLUENZAE TYPE B VACCINE (new Pharmacode listing)

> → Ini 10 mcg vial with diluent syringe – 5% DV Dec-24 to 2027 0.00 Act-HIB

Note - this listing is for Pharmacode 2697955.

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