

Pharmaceutical Management Agency
New Zealand
Pharmaceutical Schedule

Section H Update

for Hospital Pharmaceuticals

December 2019

The logo for PHARMAC, featuring the word "PHARMAC" in a bold, uppercase, sans-serif font. Below it, the Māori name "TE PĀTAKA WHAIORANGA" is written in a smaller, uppercase, sans-serif font. The logo is centered within a white circle that overlaps a background of stylized, concentric, wavy lines in shades of gray and white, resembling a stylized sun or a wave pattern.

PHARMAC
TE PĀTAKA WHAIORANGA

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Summary of decisions

EFFECTIVE 1 DECEMBER 2019

- Alectinib (Alecensa) cap 150 mg – new listing
- Ascorbic acid (Cvite) tab 100 mg – price increase and addition of HSS
- Chloramphenicol (Devatis) eye oint 1% - new listing and addition of HSS
- Chloramphenicol (Chlorsig) eye oint 1% - to be delisted 1 May 2020
- Clopidogrel (Clopidogrel Multichem) tab 75 mg – new listing and addition of HSS
- Clopidogrel (Arrow-Clopid) tab 75 mg – to be delisted 1 May 2020
- Colaspase [L-asparaginase] (Leunase) inj 10,000 iu vial – to be delisted 1 December 2020
- Danazol (Mylan) cap 100 mg – new listing
- Danazol (Azol) cap 100 mg – to be delisted 1 June 2020
- Dosulepin [dothiepin] hydrochloride (Dosulepin Mylan) cap 25 mg – new listing
- Droperidol (Droleptan) inj 2.5 mg per ml, 1 ml ampoule – new listing and addition of HSS
- Droperidol (Droperidol Panpharma) inj 2.5 mg per ml, 1 ml ampoule – to be delisted 1 May 2020
- Enteral feed with fibre 0.83 kcal/ml (Nutrison 800 Complete Multi Fibre) liquid 5.5 g protein, 8.8 g carbohydrate, 2.5 g fat and 1.5 g fibre per 100 ml, bottle – new Pharmacode listing and amended presentation description
- Flecainide acetate (Tambocor) inj 10 mg per ml, 15 ml ampoule – price increase
- Fluoxetine hydrochloride (Fluox) tab dispersible 20 mg, scored and cap 20 mg – HSS delayed and delisted
- Fluoxetine hydrochloride (Arrow-Fluoxetine) tab dispersible 20 mg, scored and cap 20 mg – delisting delayed
- Meningococcal (A, C, Y and W-135) conjugate vaccine (Menactra) inj 4 mcg or each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial – amended restriction criteria
- Methenamine (hexamine) hippurate (Hiprex) tab 1 g – new listing and amended chemical name
- Multivitamins (Mvite) tab (BPC cap strength) – price increase and addition of HSS
- Nivolumab (Opdivo) inj 10 mg per ml, 4 ml and 10 ml vial – amended restriction criteria

Summary of decisions – effective 1 December 2019 (continued)

- Ocrelizumab (Ocrevus) inj 30 mg per ml, 10 ml vial – new listing
- Pegaspargase (Oncaspar LYO) inj 750 iu per ml, 5 ml vial – new listing
- Pegaspargase (Oncaspar) inj 750 iu per ml, 5 ml vial – to be delisted 1 May 2020
- Pembrolizumab (Keytruda) inj 25 mg per ml, 4 ml vial – amended restriction criteria
- Pirfenidone (Esbriet) tab 801 mg – new listing
- Pirfenidone (Esbriet) tab 801 mg and cap 267 mg – amended restriction criteria
- Rituximab (Mabthera) inj 10 mg per ml, 10 ml vial and 50 ml vial – amended restriction criteria
- Simeticone oral drops 40 mg per ml – new listing
- Temozolomide (Temaccord) cap 5 mg – new listing and addition of HSS
- Temozolomide (Orion Temozolomide) cap 5 mg – to be delisted 1 May 2020
- Tranexamic acid (Mercury Pharma) tab 500 mg – new listing and addition of HSS
- Tranexamic acid (Cyklokapron) tab 500 mg – to be delisted 1 May 2020
- Trastuzumab emtansine (Kadcyla) inj 100 mg and 160 mg vial – new listing
- Varicella zoster vaccine [shingles vaccine] (Zostavax) varicella zoster virus (Oka strain) live attenuated vaccine [shingles vaccine] – amended restriction criteria
- Venetoclax (Venclexta) tab 10 mg, 50 mg, 100 mg and 14 x 10 mg, 7 x 50 mg, 21 x 100 mg – new listing

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

Effective 1 December 2019

ALIMENTARY TRACT AND METABOLISM

5	SIMETICONE (new listing) Oral drops 40 mg per ml			
20	MULTIVITAMINS (↑ price and addition of HSS) Tab (BPC cap strength) – 1% DV Mar-20 to 2022	11.45	1,000	Mvite
21	ASCORBIC ACID (↑ price and addition of HSS) Tab 100 mg – 1% DV Mar-20 to 2022	9.90	500	Cvite

BLOOD AND BLOOD FORMING ORGANS

27	TRANEXAMIC ACID (brand change) Tab 500 mg – 1% DV May-20 to 2022	9.45	60	Mercury Pharma
	Note – Cyklokapron tab 500 mg to be delisted from 1 May 2020.			
31	CLOPIDOGREL (brand change) Tab 75 mg – 1% DV May-20 to 2022	4.60	84	Clopidogrel Multichem
	Note – Arrow - Clopid tab 75 mg to be delisted from 1 May 2020.			

CARDIOVASCULAR SYSTEM

41	FLECAINIDE ACETATE (↑ price) Inj 10 mg per ml, 15 ml ampoule	100.00	5	Tambacor
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HORMONE PREPARATIONS

65	DANAZOL (new listing) Cap 100 mg	19.13	28	Mylan
65	DANAZOL (delisting) Cap 100 mg	68.33	100	Azol
	Note – Azol cap 100 mg to be delisted from 1 June 2020.			

INFECTIONS

79	METHENAMINE (HEXAMINE) HIPPURATE (new listing and amended chemical name) Tab 1 g	40.01	100	Hiprex
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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 December 2019 (continued)

NERVOUS SYSTEM

111	DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE (new listing) → Cap 25 mg.....	7.83	50	Dosulepin Mylan
112	FLUOXETINE HYDROCHLORIDE (HSS delayed and delisted) Tab dispersible 20 mg, scored – 1% DV Apr-20 to 2022 Cap 20 mg – 1% DV Apr-20 to 2022	1.98 2.91	30 84	Fluox Fluox
Note – Fluox tab dispersible 20 mg, scored and cap 20 mg delisted 1 December 2019 and HSS delayed until 1 August 2020.				
112	FLUOXETINE HYDROCHLORIDE (delisting delayed) Tab dispersible 20 mg, scored..... Cap 20 mg	2.47 1.99	30 90	Arrow-Fluoxetine Arrow-Fluoxetine
Note – delisting delayed from 1 April 2020 until 1 August 2020.				
116	DROPERIDOL (brand change) Inj 2.5 mg per ml, 1 ml ampoule – 1% DV May-20 to 2022	30.95	10	Droleptan
Note – Droperidol Panpharma inj 2.5 mg per ml, 1 ml ampoule to be delisted from 1 May 2020.				
121	OCRELIZUMAB (new listing) → Inj 30 mg per ml, 10 ml vial.....	9,346.00	1	Ocrevus
Restricted Initiation Only for use in patients with approval by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (set out in Section B of the Pharmaceutical Schedule).				

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

133	COLASPASE [L-ASPARAGINASE] (delisting) Inj 10,000 iu vial.....	102.32	1	Leunase
Note – Leunase inj 10,000 iu vial to be delisted from 1 December 2020.				
134	PEGASPARGASE (new listing) → Inj 750 iu per ml, 5 ml vial.....	3,005.00	1	Oncaspar LYO
134	PEGASPARGASE (delisting) → Inj 750 iu per ml, 5 ml vial.....	3,005.00	1	Oncaspar
Note – Oncaspar inj 750 iu per ml, 5 ml vial to be delisted from 1 May 2020.				
134	TEMOZOLOMIDE (brand change) → Cap 5 mg – 1% DV May-20 to 2022	9.13	5	Temaccord
Note – Orion Temozolomide cap 5 mg to be delisted from 1 May 2020.				

→ 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 December 2019 (continued)

136	ALECTINIB (new listing) → Cap 150 mg.....	7,935.00	224	Alecensa
	Restricted Initiation <i>Re-assessment required after 6 months</i> All of the following: 1 Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer; and 2 There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test; and 3 Patient has an ECOG performance score of 0-2. Continuation <i>Re-assessment required after 6 months</i> Both: 1 No evidence of progressive disease according to RECIST criteria; and 2 The patient is benefitting from and tolerating treatment.			
136	VENETOCLAX (new listing) → Tab 10 mg..... → Tab 50 mg..... → Tab 100 mg..... → Tab 14 x 10 mg, 7 x 50 mg, 21 x 100 mg	95.78 239.44 8,209.41 1,771.86	14 7 120 42	Venclexta Venclexta Venclexta Venclexta
	Restricted Initiation - relapsed/refractory chronic lymphocytic leukaemia Haematologist <i>Re-assessment required after 7 months</i> All of the following: 1 Patient has chronic lymphocytic leukaemia requiring treatment; and 2 Patient has received at least one prior therapy for chronic lymphocytic leukaemia; and 3 Patient has not previously received funded venetoclax; and 4 The patient's disease has relapsed within 36 months of previous treatment; and 5 Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and 6 Patient has an ECOG performance status of 0-2. Continuation - relapsed/refractory chronic lymphocytic leukaemia Haematologist <i>Re-assessment required after 6 months</i> Both: 1 Treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment; and 2 Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity. Initiation - previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation* Haematologist <i>Re-assessment required after 6 months</i> All of the following: 1 Patient has previously untreated chronic lymphocytic leukaemia; and 2 There is documentation confirming that patient has 17p deletion by FISH testing or TP53 mutation by sequencing; and 3 Patient has an ECOG performance status of 0-2.			

continued...

Price (ex man. Excl. GST) \$ Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

continued...

Continuation - previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Haematologist

Re-assessment required after 6 months

The treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)* and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are unapproved indications.

173	RITUXIMAB (amended restriction criteria – affected criteria shown only)		
	→ Inj 10 mg per ml, 10 ml vial.....	1,075.50	2 Mabthera
	→ Inj 10 mg per ml, 50 ml vial.....	2,688.30	1 Mabthera

Restricted

Initiation – Chronic lymphocytic leukaemia

Re-assessment required after 12 months

All of the following:

1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment;
and

2 Any of the following:

2.1 The patient is rituximab treatment naive; ~~and~~ **or**

~~2.2~~ **2.2** Either:

~~2.2.1~~ **2.2.1** The patient is chemotherapy treatment naive; or

~~2.2.2~~ **2.2.2** Both:

~~2.2.2.1~~ **2.2.2.1** The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and

~~2.2.2.2~~ **2.2.2.2** The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy;
~~and~~ **or**

2.3 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and

~~3~~ **5** The patient has good performance status; and

4 ~~Either:~~

~~4.1~~ **4.1** The patient does not have chromosome 17p deletion CLL; ~~and~~ **or**

~~4.2~~ **4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and**

~~5~~ **6** Rituximab to be administered in combination with fludarabine and cyclophosphamide, ~~or~~ bendamustine **or venetoclax** for a maximum of 6 treatment cycles; and

~~6~~ **7** It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), ~~or~~ bendamustine **or venetoclax.**

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

Continuation – Chronic lymphocytic leukaemia

Re-assessment required after 12 months

All of the following:

Both:

1 ~~Either:~~

continued...

→ 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 December 2019 (continued)

continued...

1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or

1.2 All of the following:

1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and

1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and

1.2.3 The patient does not have chromosome 17p deletion CLL; and

1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and

2.5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, or bendamustine or **venetoclax** for a maximum of 6 treatment cycles.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

188 TRASTUZUMAB EMTANSINE (new listing)

→ Inj 100 mg vial	2,320.00	1	Kadcyla
→ Inj 160 mg vial	3,712.00	1	Kadcyla

Restricted

Initiation

Re-assessment required after 6 months

All of the following:

1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and

2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and

3 Either

3.1 The patient has received prior therapy for metastatic disease*; or

3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and

4 Patient has a good performance status (ECOG 0-1); and

5 Either:

5.1 Patient does not have symptomatic brain metastases; or

5.2 Patient has brain metastases and has received prior local CNS therapy; and

6 Treatment to be discontinued at disease progression.

Continuation

Re-assessment required after 6 months

Both:

1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and

2 Treatment to be discontinued at disease progression.

*Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

188	NIVOLUMAB (amended restriction criteria)		
	→ 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 (excluding uveal) stage III or IV; and		
	2 Patient has measurable disease as defined by RECIST version 1.1 the presence of at least one CT or MRI measurable lesion; and		
	3 The patient has ECOG performance score of 0-2; and		
	4 Either:		
	4.1 Patient has not received funded pembrolizumab; or		
	4.2 Both:		
	4.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and		
	4.2.2 The cancer did not progress while the patient was on pembrolizumab; and		
	5 Nivolumab is to be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles); and		
	6 Baseline measurement of overall tumour burden is documented (see Note); and		
	7 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>		
	Either:		
	1 All of the following:		
	1.1 Any of the following:		
	1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or		
	1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or		
	1.1.3 Patient has stable disease according to RECIST criteria (see Note); and		
	1.2 Either:		
	1.2.1 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and or		
	1.2.2 Both:		
	1.2.2.1 Patient has measurable disease as defined by RECIST version 1.1; and		
	1.2.2.2 Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and		
	1.3 No evidence of progressive disease according to RECIST criteria (see Note); and		
	1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and		
	1.5 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks; or for a maximum of 12 weeks (6 cycles).		
	2 All of the following:		
	2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and		
	2.2 Patient has signs of disease progression; and		
	2.3 Disease has not progressed during previous treatment with nivolumab; 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 December 2019 (continued)

continued...

2.4 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks.

Notes: **Baseline assessment and 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. **Measurable disease includes by CT or MRI imaging or caliper measurement by clinical exam.** 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.

189 PEMBROLIZUMAB (amended restriction criteria)

→ Inj 25 mg per ml, 4 ml vial..... 4,680.00 1 Keytruda

Restricted

Initiation

Medical oncologist

Re-assessment required after 4 months

All of the following:

- 1 Patient has metastatic or unresectable melanoma (**excluding uveal**) stage III or IV; and
- 2 Patient has measurable disease as defined by **RECIST version 1.1** ~~the presence of at least one CT or MRI-measurable lesion~~; and
- 3 The patient has ECOG performance score of 0-2; and
- 4 Either:
 - 4.1 Patient has not received funded nivolumab; or
 - 4.2 Both:
 - 4.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
 - 4.2.2 The cancer did not progress while the patient was on nivolumab; and
- 5 Pembrolizumab is to be used at a maximum dose of **no greater than the equivalent of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles)**; and
- 6 Baseline measurement of overall tumour burden is documented (see Note); and
- 7 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

Either:

- 1 All of the following:

continued...

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

- 1.1 Any of the following:
 - 1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
 - 1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
 - 1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
 - 1.2 **Either:**
 - 1.2.1 ~~Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and~~ or
 - 1.2.2 **Both:**
 - 1.2.2.1 **Patient has measurable disease as defined by RECIST version 1.1; and**
 - 1.2.2.2 **Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and**
 - 1.3 No evidence of progressive disease according to RECIST criteria (see Note); and
 - 1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
 - 1.5 Pembrolizumab will be used at a maximum dose of **no greater than the equivalent of 2 mg/kg every 3 weeks; or for a maximum of 12 weeks (4 cycles).**
- 2 All of the following:**
- 2.1 **Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and**
 - 2.2 **Patient has signs of disease progression; and**
 - 2.3 **Disease has not progressed during previous treatment with pembrolizumab; and**
 - 2.4 **Pembrolizumab will be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks.**

Notes: **Baseline assessment and 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. **Measurable disease includes by CT or MRI imaging or caliper measurement by clinical exam.** 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.

RESPIRATORY SYSTEM AND ALLERGIES

196	PIRFENIDONE (new listing)			
	→ Tab 801 mg	3,645.00	90	Esbriet

	Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

196	PIRFENIDONE (amended restriction criteria)			
	→ Tab 801 mg.....	3,645.00	90	Esbriet
	→ Cap 267 mg.....	3,645.00	270	Esbriet
	Restricted			
	Initiation - idiopathic pulmonary fibrosis			
	Respiratory specialist			
	<i>Re-assessment required after 12 months</i>			
	All of the following:			
	1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and			
	2 Forced vital capacity is between 50% and 80 90% predicted; and			
	3 Pirfenidone is to be discontinued at disease progression (See Note); and			
	4 Pirfenidone is not to be used in combination with subsidised nintedanib; and			
	5 Any of the following:			
	5.1 The patient has not previously received treatment with nintedanib; or			
	5.2 Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or			
	5.3 Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).			
	Continuation - idiopathic pulmonary fibrosis			
	Respiratory specialist			
	<i>Re-assessment required after 12 months</i>			
	All of the following:			
	1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and			
	2 Pirfenidone is not to be used in combination with subsidised nintedanib; and			
	3 Pirfenidone is to be discontinued at disease progression (See Note).			
	Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.			

SENSORY ORGANS

201	CHLORAMPHENICOL (brand change)			
	Eye oint 1% – 1% DV May-20 to 2022	1.55	5 g	Devatis
	Note – Chlorsig eye oint 1% to be delisted from 1 May 2020.			

SPECIAL FOODS

232	ENTERAL FEED WITH FIBRE 0.83 KCAL/ML (Pharmacode change and amended presentation description)			
	→ Liquid 5.5 g protein, 8.8 g carbohydrate, 2.5 g fat and 1.5 g fibre per 100 ml, bottle bag	5.29	1,000 ml	Nutrison 800 Complete Multi Fibre
	Note – this is a new Pharmacode listing, 2572982. Pharmacode 2510774 to be delisted from 1 June 2020.			

Price (ex man. Excl. GST) \$	Per	Brand or Generic Manufacturer
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Changes to Section H Part II – effective 1 December 2019 (continued)

VACCINES

236 MENINGOCOCCAL (A, C, Y AND W-135) CONJUGATE VACCINE (amended restriction criteria)
 Inj 4 mcg or each meningococcal polysaccharide
 conjugated to a total of approximately 48 mcg of diphtheria
 toxoid carrier per 0.5 ml vial – **0% DV Jul-17 to 2020** 0.00 1 **Menactra**

Restricted

Initiation

Either:

1 Any of the following:

- 1 Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with HIV, complement deficiency (acquired or inherited), functional or anatomic asplenia or pre or post solid organ transplant; or
- 2 One dose for close contacts of meningococcal cases; or
- 3 A maximum of two doses for bone marrow transplant patients; or
- 4 A maximum of two doses for patients following immunosuppression*; **or**

2 Both:

1 Person is aged between 13 and 25 years, inclusive; and

2 Either

2.1 One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons; or

2.2 One dose for individuals who are currently living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons, from 1 December 2019 to 30 November 2020.

Notes: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

243 VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] (amended restriction criteria)
 → Varicella zoster virus (Oka strain) live attenuated
 vaccine [shingles vaccine] 0.00 1 Zostavax
 10 Zostavax

Restricted

Initiation – people aged between 66 and 80 years

Therapy limited to 1 dose

One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 ~~March~~ **December** 2020.

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