



**Australian Government**

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**Department of Health**

**SCHEDULE OF PHARMACEUTICAL  
BENEFITS**

**SUMMARY OF CHANGES**

**EFFECTIVE 1 March 2014**

## PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 March 2014. The Schedule is updated on the first day of each month and is available on the Internet at [www.pbs.gov.au](http://www.pbs.gov.au).

### Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 March 2014 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.63
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.67
	Allowable additional patient charge*	\$4.19
Additional Fees (for safety net prices):	Ready-prepared	\$1.13
	Extemporaneously-prepared	\$1.48
Patient Co-payments:	General	\$36.90
	Concessional	\$6.00
Safety Net Thresholds:	General	\$1421.20
	Concessional	\$360.00
Safety Net Card Issue Fee:		\$9.26

\*The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

## SUMMARY OF CHANGES

### Additions

#### Addition – Item

10036F	<b>Arachidonic Acid And Docosahexaenoic Acid With Carbohydrate</b> , arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets ( <i>keyomega</i> )
10046R	<b>Bimatoprost</b> , bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses ( <i>Lumigan PF</i> )
10053D	<b>Bimatoprost</b> , bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses ( <i>Lumigan PF</i> )
10050Y	<b>Carbohydrates, Fat, Vitamins, Minerals, Trace Elements And Supplemented With Arachidonic Acid And Docosahexaenoic Acid</b> , carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 21.5 g sachets ( <i>basecal 100</i> )
10039J	<b>Carbohydrates, Fat, Vitamins, Minerals, Trace Elements And Supplemented With Arachidonic Acid And Docosahexaenoic Acid</b> , carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories oral liquid: powder for, 30 x 43 g sachets ( <i>basecal 200</i> )
10040K	<b>Docosahexaenoic Acid With Carbohydrate</b> , docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets ( <i>docomega</i> )
10038H	<b>Linagliptin + Metformin</b> , linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Trajentamet</i> )
10045Q	<b>Linagliptin + Metformin</b> , linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 ( <i>Trajentamet</i> )
10044P	<b>Linagliptin + Metformin</b> , linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Trajentamet</i> )
10054E	<b>Pazopanib</b> , pazopanib 200 mg tablet, 30 ( <i>Votrient</i> )
10042M	<b>Pazopanib</b> , pazopanib 200 mg tablet, 90 ( <i>Votrient</i> )
10047T	<b>Pazopanib</b> , pazopanib 200 mg tablet, 90 ( <i>Votrient</i> )
10052C	<b>Pazopanib</b> , pazopanib 400 mg tablet, 30 ( <i>Votrient</i> )
10041L	<b>Pazopanib</b> , pazopanib 400 mg tablet, 60 ( <i>Votrient</i> )
10043N	<b>Pazopanib</b> , pazopanib 400 mg tablet, 60 ( <i>Votrient</i> )
10048W	<b>Saxagliptin + Metformin</b> , saxagliptin 2.5 mg + metformin hydrochloride 1 g tablet: modified release, 56 ( <i>Kombiglyze XR 2.5/1000</i> )
10055F	<b>Saxagliptin + Metformin</b> , saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28 ( <i>Kombiglyze XR 5/500</i> )
10051B	<b>Saxagliptin + Metformin</b> , saxagliptin 5 mg + metformin hydrochloride 1 g tablet: modified release, 28 ( <i>Kombiglyze XR 5/1000</i> )
10037G	<b>Triglycerides Long Chain</b> , triglycerides long chain oral liquid, 18 x 250 mL cartons ( <i>carbzero</i> )
10049X	<b>Triglycerides Medium Chain</b> , triglycerides medium chain oral liquid, 18 x 250 mL cartons ( <i>betaquik</i> )

#### Addition – Brand

5006L	<i>Clavam 875 mg/125 mg, NJ</i> – <b>Amoxicillin + Clavulanic Acid</b> , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8254K	<i>Clavam 875 mg/125 mg, NJ</i> – <b>Amoxicillin + Clavulanic Acid</b> , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8179L	<i>Azastrole, ER</i> – <b>Anastrozole</b> , anastrozole 1 mg tablet, 30
8094B	<i>Bicalox, ER</i> – <b>Bicalutamide</b> , bicalutamide 50 mg tablet, 28
2546B	<i>Aldiq, QA</i> – <b>Imiquimod</b> , imiquimod 5% (12.5 mg/250 mg) cream, 12 x 250 mg sachets
2456G	<i>Auro-Lisinopril 5, DO</i> – <b>Lisinopril</b> , lisinopril 5 mg tablet, 30
2457H	<i>Auro-Lisinopril 10, DO</i> – <b>Lisinopril</b> , lisinopril 10 mg tablet, 30
2458J	<i>Auro-Lisinopril 20, DO</i> – <b>Lisinopril</b> , lisinopril 20 mg tablet, 30
8007K	<i>Topra 40, DO</i> – <b>Pantoprazole</b> , pantoprazole 40 mg tablet: enteric, 30
8008L	<i>Topra 40, DO</i> – <b>Pantoprazole</b> , pantoprazole 40 mg tablet: enteric, 30
3169T	<i>Rispernia, ER</i> – <b>Risperidone</b> , risperidone 1 mg tablet, 60
8789N	<i>Rispernia, ER</i> – <b>Risperidone</b> , risperidone 1 mg tablet, 60
3170W	<i>Rispernia, ER</i> – <b>Risperidone</b> , risperidone 2 mg tablet, 60
9079W	<i>Rispernia, ER</i> – <b>Risperidone</b> , risperidone 2 mg tablet, 60
3171X	<i>Rispernia, ER</i> – <b>Risperidone</b> , risperidone 3 mg tablet, 60
3172Y	<i>Rispernia, ER</i> – <b>Risperidone</b> , risperidone 4 mg tablet, 60
8787L	<i>Rispernia, ER</i> – <b>Risperidone</b> , risperidone 500 microgram tablet, 60
8869T	<i>Rispernia, ER</i> – <b>Risperidone</b> , risperidone 500 microgram tablet, 60
8836C	<i>Sertraline Actavis, UA</i> – <b>Sertraline</b> , sertraline 50 mg tablet, 30
8837D	<i>Sertraline Actavis, UA</i> – <b>Sertraline</b> , sertraline 100 mg tablet, 30
8378Y	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 5 mg capsule, 5
8819E	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 5 mg capsule, 5
8379B	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 20 mg capsule, 5
8820F	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 20 mg capsule, 5
8380C	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 100 mg capsule, 5
8821G	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 100 mg capsule, 5
9362R	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 140 mg capsule, 5
9361Q	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 140 mg capsule, 5
8381D	<i>Temozolomide Alphapharm, AF</i> – <b>Temozolomide</b> , temozolomide 250 mg capsule, 5

## Deletions

### Deletion – Item

8545R	<b>Amino Acid Formula With Vitamins And Minerals Without Phenylalanine</b> , amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 400 g ( <i>Phenex-2</i> )
5455D	<b>Degarelix</b> , degarelix 80 mg injection: subcutaneous infusion [1 x 80 mg vial] (&) inert substance diluent [1 x 4.2 mL vial], 1 pack ( <i>Firmagon 80mg</i> )
5456E	<b>Degarelix</b> , degarelix 120 mg injection: subcutaneous infusion [2 x 120 mg vials] (&) inert substance diluent [2 x 3 mL vials], 1 pack ( <i>Firmagon 120mg</i> )
1252X	<b>Terbutaline</b> , terbutaline sulfate 500 microgram/actuation inhalation: powder for, 200 actuations ( <i>Bricanyl Turbuhaler</i> )

### Deletion – Brand

2751T	<i>Amlodipine Pfizer, FZ</i> – <b>Amlodipine</b> , amlodipine 5 mg tablet, 30
2752W	<i>Amlodipine Pfizer, FZ</i> – <b>Amlodipine</b> , amlodipine 10 mg tablet, 30
5097G	<i>Diclocil, BQ</i> – <b>Dicloxacillin</b> , dicloxacillin 500 mg capsule, 24
8122L	<i>Diclocil, BQ</i> – <b>Dicloxacillin</b> , dicloxacillin 500 mg capsule, 24
8505P	<i>Gabapentin Pfizer, FZ</i> – <b>Gabapentin</b> , gabapentin 100 mg capsule, 100
1834M	<i>Gabapentin Pfizer, FZ</i> – <b>Gabapentin</b> , gabapentin 300 mg capsule, 100
1835N	<i>Gabapentin Pfizer, FZ</i> – <b>Gabapentin</b> , gabapentin 400 mg capsule, 100
8389M	<i>Gabapentin Pfizer, FZ</i> – <b>Gabapentin</b> , gabapentin 800 mg tablet, 100
3064G	<i>Lactocur, SZ</i> – <b>Lactulose</b> , LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1
5388N	<i>Lactocur, SZ</i> – <b>Lactulose</b> , LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 ( <b>Palliative Care</b> )
5387M	<i>Lactocur, SZ</i> – <b>Lactulose</b> , LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 ( <b>Palliative Care</b> )
8170B	<i>Zylap 2.5, QA</i> – <b>Olanzapine</b> , olanzapine 2.5 mg tablet, 28
8185T	<i>Zylap 5, QA</i> – <b>Olanzapine</b> , olanzapine 5 mg tablet, 28
8186W	<i>Zylap 7.5, QA</i> – <b>Olanzapine</b> , olanzapine 7.5 mg tablet, 28
8187X	<i>Zylap 10, QA</i> – <b>Olanzapine</b> , olanzapine 10 mg tablet, 28
3381Y	<i>Zylap ODT 5, QA</i> – <b>Olanzapine</b> , OLANZAPINE Tablet 5 mg (orally disintegrating), 28
3382B	<i>Zylap ODT 10, QA</i> – <b>Olanzapine</b> , OLANZAPINE Tablet 10 mg (orally disintegrating), 28
1968N	<i>Quinapril Pfizer, FZ</i> – <b>Quinapril</b> , quinapril 5 mg tablet, 30
1969P	<i>Quinapril Pfizer, FZ</i> – <b>Quinapril</b> , quinapril 10 mg tablet, 30
1970Q	<i>Quinapril Pfizer, FZ</i> – <b>Quinapril</b> , quinapril 20 mg tablet, 30
8836C	<i>Sertraline Pfizer, FZ</i> – <b>Sertraline</b> , sertraline 50 mg tablet, 30
2236Q	<i>Sertraline Pfizer, FZ</i> – <b>Sertraline</b> , sertraline 50 mg tablet, 30
8837D	<i>Sertraline Pfizer, FZ</i> – <b>Sertraline</b> , sertraline 100 mg tablet, 30
2237R	<i>Sertraline Pfizer, FZ</i> – <b>Sertraline</b> , sertraline 100 mg tablet, 30

### Deletion – Equivalence Indicator

8122L	<i>Distaph 500, AF</i> – <b>Dicloxacillin</b> , dicloxacillin 500 mg capsule, 24
5097G	<i>Distaph 500, AF</i> – <b>Dicloxacillin</b> , dicloxacillin 500 mg capsule, 24

## Alterations

### Alteration – Brand Name

<i>From:</i>	
2236Q	<i>Sertraline-GA, UA</i> – <b>Sertraline</b> , sertraline 50 mg tablet, 30
<i>To:</i>	
2236Q	<i>Sertraline Actavis, UA</i> – <b>Sertraline</b> , sertraline 50 mg tablet, 30
<i>From:</i>	
2237R	<i>Sertraline-GA, UA</i> – <b>Sertraline</b> , sertraline 100 mg tablet, 30
<i>To:</i>	
2237R	<i>Sertraline Actavis, UA</i> – <b>Sertraline</b> , sertraline 100 mg tablet, 30

### Alteration – Restriction

8369L	<b>Carbohydrate, Fat, Vitamins, Minerals And Trace Elements</b> , carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g ( <i>Energivit</i> )
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### Alteration – Manufacturer's Code

		<i>From</i>	<i>To</i>
2361G	<i>Plendil ER, GX</i> – <b>Felodipine</b> , felodipine 2.5 mg tablet: modified release, 30 tablets	AP	GX
2366M	<i>Plendil ER, GX</i> – <b>Felodipine</b> , felodipine 5 mg tablet: modified release, 30 tablets	AP	GX
2367N	<i>Plendil ER, GX</i> – <b>Felodipine</b> , felodipine 10 mg tablet: modified release, 30 tablets	AP	GX

## Advance Notices

### Advance Notices – Deletion of Item

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2014:

2745L **Tropisetron**, tropisetron 5 mg capsule, 2 (*Navoban*)

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 May 2014:

2826R **Methysergide**, methysergide 1 mg tablet, 50 (*Deseril*)

1278G **Timolol**, timolol 0.25% (2.5 mg/mL) eye drops, 5 mL (*Tenopt*)

5547Y **Timolol**, timolol 0.25% (2.5 mg/mL) eye drops, 5 mL (*Tenopt*)

### Advance Notices – Deletion of Brand

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2014:

2746M *Navoban, NV* – **Tropisetron**, tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule

## SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

### Additions

#### Addition – Brand

9506H *Nevipin, GN* – **Nevirapine**, nevirapine 200 mg tablet, 60 (**Public**)

6215D *Nevipin, GN* – **Nevirapine**, nevirapine 200 mg tablet, 60 (**Private**)

## SECTION 100 – BOTULINUM TOXIN PROGRAM

### Alterations

#### Alteration – Restriction

6103F **Botulinum Toxin Type A**, botulinum toxin type A 100 units injection, 1 x 100 units vial (*Botox*)

## SECTION 100 – HUMAN GROWTH HORMONE

### Deletions

#### Deletion – Item

6330E **Somatropin**, somatropin 15 international units (5 mg) injection [1 x 5 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack (*Genotropin*)

## REPATRIATION PHARMACEUTICAL BENEFITS

### Deletions

#### Deletion – Brand

4444X *Chem mart Risedronate, CH* – **Risedronate**, risedronate sodium 35 mg tablet, 4

4444X *Terry White Chemists Risedronate, TW* – **Risedronate**, risedronate sodium 35 mg tablet, 4

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE</b>								
<b><u>Authority required</u></b>								
Peroxisomal biogenesis disorders								
10036F NP	arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets	4	5	..	*371.03	36.90	keyomega	VF
<b>BIMATOPROST</b>								
10046R	bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses	‡1	5	..	36.78	36.90	Lumigan PF	AG
<b>BIMATOPROST</b>								
<b><u>Note</u></b>								
<b>Shared Care Model:</b>								
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
10053D OP	bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses	‡1	5	..	36.78	36.90	Lumigan PF	AG
<b>CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS</b>								
<b><u>Restricted benefit</u></b>								
Proven inborn errors of protein metabolism								
<b>Clinical criteria:</b>								
Patient must be unable to meet their energy requirements with permitted food and formulae.								
8369L NP	carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g	8	5	..	*318.39	36.90	Energivit	SB
<b>CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID</b>								
<b><u>Restricted benefit</u></b>								
Proven inborn errors of protein metabolism								
<b>Clinical criteria:</b>								
Patient must be unable to meet their energy requirements with permitted food and formulae.								
10050Y NP	carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 21.5 g sachets	4	5	..	*248.47	36.90	basecal 100	VF
10039J NP	carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories oral liquid: powder for, 30 x 43 g sachets	4	5	..	*472.35	36.90	basecal 200	VF
<b>DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE</b>								
<b><u>Authority required</u></b>								
Peroxisomal biogenesis disorders								
10040K NP	docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets	4	5	..	*371.03	36.90	docomega	VF
<b>LINAGLIPTIN + METFORMIN</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4423</b>								
Diabetes mellitus type 2								
<b>Clinical criteria:</b>								
Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR								

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

### **Authority required (STREAMLINED)**

**4448**

Diabetes mellitus type 2

Treatment Phase: Continuing

#### **Clinical criteria:**

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.

#### **Note**

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

10038H NP	linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60	1	5	..	65.38	36.90	Trajentamet	BY
10045Q NP	linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60	1	5	..	67.08	36.90	Trajentamet	BY
10044P NP	linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60	1	5	..	67.78	36.90	Trajentamet	BY

### **PAZOPANIB**

#### **Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

#### **Clinical criteria:**

Patient must have previously been issued with an authority prescription for pazopanib,

#### **AND**

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),

#### **AND**

Patient must require dose adjustment,

#### **AND**

The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

#### **Note**

Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Stable disease (SD) is small changes that do not meet above criteria.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Special Pricing Arrangements apply.

10054E	pazopanib 200 mg tablet, 30	1	5	..	1256.46	36.90	Votrient	GK
10052C	pazopanib 400 mg tablet, 30	1	5	..	2410.21	36.90	Votrient	GK

**PAZOPANIB**

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Initial treatment

**Clinical criteria:**

Patient must have a WHO performance status of 2 or less,

**AND**

Patient must have received prior chemotherapy treatment including an anthracycline,

**AND**

Patient must not have received prior treatment with an angiogenesis inhibitor,

**AND**

The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:

adipocytic soft tissue sarcoma;

gastrointestinal stromal tumour (GIST);

rhabdomyosarcoma other than alveolar or pleomorphic;

chondrosarcoma;

osteosarcoma;

Ewings tumour/primitive neuroectodermal tumour;

dermofibromatosis sarcoma protuberans;

inflammatory myofibroblastic sarcoma;

malignant mesothelioma;

mixed mesodermal tumour of the uterus.

The authority application must be made in writing.

**Note**

No increase in the maximum quantity or number of units may be authorised.

**Note**

No increase in the maximum number of repeats may be authorised.

**Note**

Special Pricing Arrangements apply.

10042M	pazopanib 200 mg tablet, 90	1	2	..	3542.03	36.90	Votrient	GK
10041L	pazopanib 400 mg tablet, 60	1	2	..	4673.85	36.90	Votrient	GK

**PAZOPANIB**

**Authority required**

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

**Clinical criteria:**

Patient must have previously been issued with an authority prescription for pazopanib,

**AND**

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
<p>Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST),</p> <p><b>AND</b></p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Applications for continuing therapy may be made by telephone.</p> <p><b>Note</b></p> <p>Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:</p> <p>Complete response (CR) is disappearance of all target lesions.</p> <p>Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.</p> <p>Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.</p> <p>Stable disease (SD) is small changes that do not meet above criteria.</p> <p><b>Note</b></p> <p>No increase in the maximum quantity or number of units may be authorised.</p> <p><b>Note</b></p> <p>No increase in the maximum number of repeats may be authorised.</p> <p><b>Note</b></p> <p>Special Pricing Arrangements apply.</p>							
10047T	pazopanib 200 mg tablet, 90	1	5	..	3542.03	36.90	Votrient GK
10043N	pazopanib 400 mg tablet, 60	1	5	..	4673.85	36.90	Votrient GK

### SAXAGLIPTIN + METFORMIN

#### **Authority required (STREAMLINED)**

##### **4423**

Diabetes mellitus type 2

#### **Clinical criteria:**

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

#### **Authority required (STREAMLINED)**

##### **4451**

Diabetes mellitus type 2

Treatment Phase: Continuing

#### **Clinical criteria:**

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin.

#### **Note**

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in

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combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.								
10048W NP	saxagliptin 2.5 mg + metformin hydrochloride 1 g tablet: modified release, 56	1	5	..	63.70	36.90	Kombiglyze XR 2.5/1000	BQ
10055F NP	saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28	1	5	..	60.27	36.90	Kombiglyze XR 5/500	BQ
10051B NP	saxagliptin 5 mg + metformin hydrochloride 1 g tablet: modified release, 28	1	5	..	61.47	36.90	Kombiglyze XR 5/1000	BQ
<b>TRIGLYCERIDES LONG CHAIN</b>								
<b><u>Restricted benefit</u></b>								
Ketogenic diet								
<b>Clinical criteria:</b>								
Patient must have intractable seizures requiring treatment with a ketogenic diet; OR								
Patient must have a glucose transport protein defect; OR								
Patient must have pyruvate dehydrogenase deficiency.								
Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.								
<b><u>Note</u></b>								
Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.								
10037G NP	triglycerides long chain oral liquid, 18 x 250 mL cartons	2	5	..	*300.03	36.90	carbzero	VF
<b>TRIGLYCERIDES MEDIUM CHAIN</b>								
<b><u>Authority required</u></b>								
Ketogenic diet								
<b>Clinical criteria:</b>								
Patient must have intractable seizures requiring treatment with a ketogenic diet; OR								
Patient must have a glucose transport protein defect; OR								
Patient must have pyruvate dehydrogenase deficiency.								
<b><u>Authority required</u></b>								
Dietary management of conditions requiring a source of medium chain triglycerides								
<b>Clinical criteria:</b>								
Patient must have chylous ascites; OR								
Patient must have chylothorax; OR								
Patient must have hyperlipoproteinaemia type 1; OR								
Patient must have long chain fatty acid oxidation disorders; OR								
Patient must have fat malabsorption due to liver disease; OR								
Patient must have fat malabsorption due to short gut syndrome; OR								
Patient must have fat malabsorption due to cystic fibrosis; OR								
Patient must have fat malabsorption due to gastrointestinal disorders.								
<b><u>Note</u></b>								
No increase in the maximum quantity or number of units may be authorised.								
<b><u>Note</u></b>								
No increase in the maximum number of repeats may be authorised.								
10049X NP	triglycerides medium chain oral liquid, 18 x 250 mL cartons	2	5	..	*383.73	36.90	betaquik	VF

## SECTION 100 (BOTULINUM TOXIN PROGRAM)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer
	<p><b>BOTULINUM TOXIN TYPE A</b></p> <p><b><u>Criteria for availability</u></b> Blepharospasm or hemifacial spasm</p> <p><b>Population criteria:</b> Patient must be aged 12 years or older.</p> <p><b><u>Note</u></b> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b><u>Note</u></b> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b><u>Criteria for availability</u></b> Dynamic equinus foot deformity</p> <p><b>Clinical criteria:</b> The condition must be due to spasticity,</p> <p><b>AND</b> Patient must be an ambulant cerebral palsy patient.</p> <p><b>Population criteria:</b> Patient must be aged from 2 to 17 years inclusive.</p> <p><b><u>Note</u></b> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b><u>Note</u></b> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b><u>Criteria for availability</u></b> Dynamic equinus foot deformity</p> <p><b>Clinical criteria:</b> The condition must be due to spasticity,</p> <p><b>AND</b> Patient must be an ambulant cerebral palsy patient,</p> <p><b>AND</b> Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.</p> <p><b>Population criteria:</b> Patient must be aged 18 years or older.</p> <p><b><u>Note</u></b> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b><u>Note</u></b> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b><u>Criteria for availability</u></b> Spasmodic torticollis</p> <p><b>Clinical criteria:</b> The treatment must be as monotherapy; OR The treatment must be as adjunctive therapy to current standard care.</p> <p><b><u>Note</u></b> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b><u>Note</u></b> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b><u>Criteria for availability</u></b> Moderate to severe spasticity of the upper limb</p> <p><b>Clinical criteria:</b> Patient must have cerebral palsy.</p> <p><b>Population criteria:</b> Patient must be aged from 2 to 17 years inclusive.</p> <p><b><u>Note</u></b></p>			

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	Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.			
	<p><b><u>Note</u></b> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b><u>Criteria for availability</u></b> Moderate to severe spasticity of the upper limb</p> <p><b>Clinical criteria:</b> Patient must have cerebral palsy,</p> <p><b>AND</b> Patient must have commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient.</p> <p><b>Population criteria:</b> Patient must be aged 18 years or older.</p> <p><b><u>Note</u></b> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b><u>Note</u></b> Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.</p> <p><b><u>Note</u></b> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b><u>Criteria for availability</u></b> Moderate to severe spasticity of the upper limb following a stroke</p> <p><b>Clinical criteria:</b> The treatment must be used as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.</p> <p><b>Population criteria:</b> Patient must be an adult. Moderate to severe spasticity is defined as MAS greater than or equal to 3 using modified Ashworth scale. Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments. The date of the stroke must be provided. Contraindications to treatment include established severe contracture and known sensitivity to botulinum toxin.</p> <p><b><u>Note</u></b> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b><u>Note</u></b> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b><u>Criteria for availability</u></b> Severe primary axillary hyperhidrosis</p> <p><b>Clinical criteria:</b> Patient must have previously failed or be intolerant to topical aluminium chloride hexahydrate after one to two months of treatment.</p> <p><b>Population criteria:</b> Patient must be aged 12 years or older. Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.</p> <p><b><u>Note</u></b> Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b><u>Note</u></b> The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b><u>Note</u></b> Special Pricing Arrangements apply.</p> <p><b><u>Criteria for availability</u></b> Urinary incontinence</p> <p><b>Clinical criteria:</b> The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study,</p>			

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	<p><b>AND</b></p> <p>The condition must be inadequately controlled by anti-cholinergic therapy,</p> <p><b>AND</b></p> <p>Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin,</p> <p><b>AND</b></p> <p>The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment,</p> <p><b>AND</b></p> <p>Patient must be willing and able to self-catheterise.</p> <p><b>Population criteria:</b></p> <p>Patient must have multiple sclerosis; OR</p> <p>Patient must have a spinal cord injury; OR</p> <p>Patient must be aged 18 years or older and have spina bifida.</p> <p><b>Note</b></p> <p>Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b>Note</b></p> <p>The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b>Note</b></p> <p>Special Pricing Arrangements apply.</p> <p><b>Criteria for availability</b></p> <p>Chronic migraine</p> <p><b>Clinical criteria:</b></p> <p>Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin,</p> <p><b>AND</b></p> <p>Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin,</p> <p><b>AND</b></p> <p>Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment.</p> <p><b>Population criteria:</b></p> <p>Patient must be an adult.</p> <p>Medication overuse headache must be appropriately managed prior to initiation of treatment with botulinum toxin.</p> <p><b>Note</b></p> <p>Arrangements to prescribe this item should be made by medical practitioners with the Department of Human Services, contact telephone number 1800 700 270.</p> <p><b>Note</b></p> <p>The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.</p> <p><b>Note</b></p> <p>Special Pricing Arrangements apply.</p>			
6103F	botulinum toxin type A 100 units injection, 1 x 100 units vial	1	415.50	Botox
				AG