



**Australian Government**

**Department of Health**



# Schedule of Pharmaceutical Benefits

Summary of Changes

**Effective 1 September 2016**



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# Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 September 2016 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.02
	Dangerous drug fee	\$2.95
	Extemporaneously-prepared	\$9.06
	Allowable additional patient charge*	\$4.33
Additional Fees (for safety net prices):	Ready-prepared	\$1.19
	Extemporaneously-prepared	\$1.55
Patient Co-payments:	General	\$38.30
	Concessional	\$6.20
Safety Net Thresholds:	General	\$1475.70
	Concessional	\$372.00
Safety Net Card Issue Fee:		\$9.61

\* 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.

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# Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 2016. 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).

## Prescriber Bag

### Deletions

#### *Deletion – Brand*

- 3496B *GenRx Salbutamol, GX* – **SALBUTAMOL**, salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules  
3497C *GenRx Salbutamol, GX* – **SALBUTAMOL**, salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

## General Pharmaceutical Benefits

### Additions

#### *Addition – Item*

- 10888C **EXENATIDE**, exenatide 2 mg/dose injection: modified release, 4 injection devices (*Bydureon*)  
10889D **LOPERAMIDE**, loperamide hydrochloride 2 mg capsule, 12 (*Gastrex, Gastro-Stop Loperamide, Imodium*)

#### *Addition – Brand*

- 8188Y *GLYBOSAY, RW* – **ACARBOSE**, acarbose 50 mg tablet, 90  
8189B *GLYBOSAY, RW* – **ACARBOSE**, acarbose 100 mg tablet, 90  
1434L *FLUOTEX, RF* – **FLUOXETINE**, fluoxetine 20 mg capsule, 28  
10792B *Elocon Alcohol Free, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g  
10809X *Elocon Alcohol Free, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g  
10815F *Elocon Alcohol Free, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g  
10818J *Elocon Alcohol Free, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g  
10827W *Elocon Alcohol Free, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g  
1913Q *Elocon Alcohol Free, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g  
9202H *APO-Quetiapine XR, TX* – **QUETIAPINE**, quetiapine 50 mg modified release tablet, 60  
9372G *APO-Valsartan HCTZ 80/12.5, TX* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28  
9374J *APO-Valsartan HCTZ 160/25, TX* – **VALSARTAN + HYDROCHLOROTHIAZIDE**, valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

### Deletions

#### *Deletion – Item*

- 10621B **HONEY BEE VENOM**, bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack (*Hymenoptera Honey Bee Venom*)  
8423H **HYDROMORPHONE**, hydromorphone hydrochloride 500 mg/50 mL injection, 50 mL vial (*Dilaudid-HP*)  
1703P **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg tablet, 25 (*Abbocillin-VK Filmtab*)

1787C **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg tablet, 25 (*Abbecillin-VK Filmstab*)  
 3360W **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 250 mg tablet, 25 (*Abbecillin-VK Filmstab*) (**Dental**)  
 3028J **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 500 mg tablet, 25 (*Abbecillin-VK Filmstab*)  
 3361X **PHENOXYMETHYLPENICILLIN**, phenoxymethylpenicillin 500 mg tablet, 25 (*Abbecillin-VK Filmstab*) (**Dental**)

**Deletion – Brand**

8511Y *Alendronate-GA, ED* – **ALENDRONATE**, alendronate 70 mg tablet, 4  
 8094B *Bicalutamide-GA, ED* – **BICALUTAMIDE**, bicalutamide 50 mg tablet, 28  
 2502Q *Calcitriol-GA, ED* – **CALCITRIOL**, calcitriol 0.25 microgram capsule, 100  
 8295N *Candesartan-GA, ED* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30  
 8296P *Candesartan-GA, ED* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30  
 8297Q *Candesartan RBX, RA* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30  
 8297Q *Candesartan-GA, ED* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30  
 8889W *Candesartan RBX, RA* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30  
 8889W *Candesartan-GA, ED* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30  
 8504N *Candesartan HCTZ RBX 16/12.5, RA* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30  
 8504N *Candesartan HCTZ-GA 16/12.5, ED* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30  
 9314F *Candesartan HCTZ-GA 32/12.5, ED* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30  
 9315G *Candesartan HCTZ-GA 32/25, ED* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30  
 8361C *Capecitabine Actavis, ED* – **CAPECITABINE**, capecitabine 150 mg tablet, 60  
 8362D *Capecitabine Actavis, ED* – **CAPECITABINE**, capecitabine 500 mg tablet, 120  
 8255L *GN-Carvedilol, ED* – **CARVEDILOL**, carvedilol 3.125 mg tablet, 30  
 8256M *GN-Carvedilol, ED* – **CARVEDILOL**, carvedilol 6.25 mg tablet, 60  
 8257N *GN-Carvedilol, ED* – **CARVEDILOL**, carvedilol 12.5 mg tablet, 60  
 8258P *GN-Carvedilol, ED* – **CARVEDILOL**, carvedilol 25 mg tablet, 60  
 1209P *Ciprofloxacin-GA, ED* – **CIPROFLOXACIN**, ciprofloxacin 500 mg tablet, 14  
 1210Q *Ciprofloxacin-GA, ED* – **CIPROFLOXACIN**, ciprofloxacin 750 mg tablet, 14  
 8702B *Citalopram-GA, ED* – **CITALOPRAM**, citalopram 10 mg tablet, 28  
 8220P *Citalopram-GA, EF* – **CITALOPRAM**, citalopram 20 mg tablet, 28  
 8703C *Citalopram-GA, EF* – **CITALOPRAM**, citalopram 40 mg tablet, 28  
 1211R *Serophene, SG* – **CLOMIPHENE**, clomiphene citrate 50 mg tablet, 10  
 1269T *Procur, ED* – **CYPROTERONE**, cyproterone acetate 50 mg tablet, 20  
 1270W *Procur, ED* – **CYPROTERONE**, cyproterone acetate 50 mg tablet, 50  
 1335G *Dilzem 60 mg, EF* – **DILTIAZEM**, diltiazem hydrochloride 60 mg tablet, 90  
 10779H *Doxy-100, ED* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7  
 2702F *Doxy-100, ED* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7  
 2709N *Doxy-100, ED* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7  
 2714W *Doxy-100, ED* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7  
 3321T *Doxy-100, ED* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7 (**Dental**)  
 9155W *Drulox, ED* – **DULOXETINE**, duloxetine 30 mg enteric capsule, 28  
 9156X *Drulox, ED* – **DULOXETINE**, duloxetine 60 mg enteric capsule, 28  
 8700X *Escitalopram GA, ED* – **ESCITALOPRAM**, escitalopram 10 mg tablet, 28

8701Y *Escitalopram GA, ED* – **ESCITALOPRAM**, escitalopram 20 mg tablet, 28

10103R *Exemestane-GA, ED* – **EXEMESTANE**, exemestane 25 mg tablet, 30

8506Q *Exemestane-GA, ED* – **EXEMESTANE**, exemestane 25 mg tablet, 30

2487X *Chem mart Famotidine, CH* – **FAMOTIDINE**, famotidine 20 mg tablet, 60

2487X *Terry White Chemists Famotidine, TW* – **FAMOTIDINE**, famotidine 20 mg tablet, 60

2488Y *Chem mart Famotidine, CH* – **FAMOTIDINE**, famotidine 40 mg tablet, 30

2488Y *Terry White Chemists Famotidine, TW* – **FAMOTIDINE**, famotidine 40 mg tablet, 30

2414C *Frusid, EA* – **FRUSEMIDE**, frusemide 20 mg tablet, 100

2412Y *Frusid, EA* – **FRUSEMIDE**, frusemide 40 mg tablet, 100

8535F *Oziclide MR, RA* – **GLICLAZIDE**, gliclazide 30 mg modified release tablet, 100

8450R *Glimepiride GA 1, ED* – **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30

8451T *Glimepiride GA 2, ED* – **GLIMEPIRIDE**, glimepiride 2 mg tablet, 30

8533D *Glimepiride GA 3, ED* – **GLIMEPIRIDE**, glimepiride 3 mg tablet, 30

8452W *Glimepiride GA 4, ED* – **GLIMEPIRIDE**, glimepiride 4 mg tablet, 30

1512N *Hydroxychloroquine Actavis, ED* – **HYDROXYCHLOROQUINE**, hydroxychloroquine sulfate 200 mg tablet, 100

2420J *Tolerade 10, PQ* – **IMIPRAMINE**, imipramine hydrochloride 10 mg tablet, 50

2421K *Tolerade 25, PQ* – **IMIPRAMINE**, imipramine hydrochloride 25 mg tablet, 50

2436F *Indapamide-GA, ED* – **INDAPAMIDE**, indapamide hemihydrate 2.5 mg tablet, 90

8246B *Irbesartan-GA, EF* – **IRBESARTAN**, irbesartan 75 mg tablet, 30

8247C *Irbesartan-GA, EF* – **IRBESARTAN**, irbesartan 150 mg tablet, 30

8248D *Irbesartan-GA, EF* – **IRBESARTAN**, irbesartan 300 mg tablet, 30

8404H *Irbesartan HCTZ-GA 150/12.5, EF* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

8405J *Irbesartan HCTZ-GA 300/12.5, EF* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

2136K *Irbesartan HCTZ-GA 300/25, EF* – **IRBESARTAN + HYDROCHLOROTHIAZIDE**, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

1558B *Imtrate 60 mg, ED* – **ISOSORBIDE MONONITRATE**, isosorbide mononitrate 60 mg modified release tablet, 30

2848X *Lamotrigine-GA, ED* – **LAMOTRIGINE**, lamotrigine 25 mg tablet, 56

2849Y *Lamotrigine-GA, ED* – **LAMOTRIGINE**, lamotrigine 50 mg tablet, 56

2850B *Lamotrigine-GA, ED* – **LAMOTRIGINE**, lamotrigine 100 mg tablet, 56

2851C *Lamotrigine-GA, ED* – **LAMOTRIGINE**, lamotrigine 200 mg tablet, 56

2456G *Lisinopril-GA, ED* – **LISINOPRIL**, lisinopril 5 mg tablet, 30

2457H *Lisinopril-GA, ED* – **LISINOPRIL**, lisinopril 10 mg tablet, 30

2458J *Lisinopril-GA, ED* – **LISINOPRIL**, lisinopril 20 mg tablet, 30

1801T *Metformin Ranbaxy, RA* – **METFORMIN**, metformin hydrochloride 850 mg tablet, 60

1207M *Metoclopramide Actavis, ED* – **METOCLOPRAMIDE**, metoclopramide hydrochloride 10 mg tablet, 25

5151D *Metoclopramide Actavis, ED* – **METOCLOPRAMIDE**, metoclopramide hydrochloride 10 mg tablet, 25 (**Dental**)

1324Q *Metoprolol Actavis, ED* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 50 mg, 100

1325R *Metoprolol Actavis, ED* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 100 mg, 60

10792B *Elocon, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g

10809X *Elocon, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g

10815F *Elocon, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g

10818J *Elocon, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g

10827W *Elocon, MK* – **MOMETASONE**, mometasone furoate 0.1% cream, 15 g

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1913Q	<i>Elocon, MK</i> – <b>MOMETASONE</b> , mometasone furoate 0.1% cream, 15 g
8627C	<i>Montair 4, ED</i> – <b>MONTELUKAST</b> , montelukast 4 mg tablet: chewable, 28
8628D	<i>Montair 5, ED</i> – <b>MONTELUKAST</b> , montelukast 5 mg tablet: chewable, 28
8170B	<i>Olanzapine-GA, ED</i> – <b>OLANZAPINE</b> , olanzapine 2.5 mg tablet, 28
3381Y	<i>Olanzapine-GA ODT, ED</i> – <b>OLANZAPINE</b> , OLANZAPINE Tablet 5 mg (orally disintegrating), 28
8185T	<i>Olanzapine-GA, ED</i> – <b>OLANZAPINE</b> , olanzapine 5 mg tablet, 28
8186W	<i>Olanzapine-GA, ED</i> – <b>OLANZAPINE</b> , olanzapine 7.5 mg tablet, 28
3382B	<i>Olanzapine-GA ODT, ED</i> – <b>OLANZAPINE</b> , OLANZAPINE Tablet 10 mg (orally disintegrating), 28
8187X	<i>Olanzapine-GA, ED</i> – <b>OLANZAPINE</b> , olanzapine 10 mg tablet, 28
1326T	<i>Omepro-GA, EA</i> – <b>OMEPRAZOLE</b> , omeprazole 20 mg capsule, 30
1327W	<i>Omepro-GA, EA</i> – <b>OMEPRAZOLE</b> , omeprazole 20 mg capsule, 30
8331L	<i>Omeprazole-GA, ED</i> – <b>OMEPRAZOLE</b> , omeprazole 20 mg tablet: enteric, 30
8333N	<i>Omeprazole-GA, ED</i> – <b>OMEPRAZOLE</b> , omeprazole 20 mg tablet: enteric, 30
8399C	<i>Pantoprazole-GA, EF</i> – <b>PANTOPRAZOLE</b> , pantoprazole 20 mg tablet: enteric, 30
8007K	<i>Pantoprazole-GA, EF</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg tablet: enteric, 30
8008L	<i>Pantoprazole-GA, EF</i> – <b>PANTOPRAZOLE</b> , pantoprazole 40 mg tablet: enteric, 30
2242B	<i>Paroxetine Actavis, ED</i> – <b>PAROXETINE</b> , paroxetine 20 mg tablet, 30
5012T	<i>Abbecillin-V, QA</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL <b>(Dental)</b>
9143F	<i>Abbecillin-V, QA</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL
8694N	<i>Pioglitazone-GA, ED</i> – <b>PIOGLITAZONE</b> , pioglitazone 15 mg tablet, 28
8695P	<i>Pioglitazone-GA, ED</i> – <b>PIOGLITAZONE</b> , pioglitazone 30 mg tablet, 28
8695P	<i>Pizaccord, RA</i> – <b>PIOGLITAZONE</b> , pioglitazone 30 mg tablet, 28
8696Q	<i>Pioglitazone-GA, ED</i> – <b>PIOGLITAZONE</b> , pioglitazone 45 mg tablet, 28
2833D	<i>Pravastatin-GA 10, ED</i> – <b>PRAVASTATIN</b> , pravastatin sodium 10 mg tablet, 30
9237E	<i>Pravastatin-GA 10, ED</i> – <b>PRAVASTATIN</b> , pravastatin sodium 10 mg tablet, 30
2834E	<i>Pravastatin-GA 20, ED</i> – <b>PRAVASTATIN</b> , pravastatin sodium 20 mg tablet, 30
9238F	<i>Pravastatin-GA 20, ED</i> – <b>PRAVASTATIN</b> , pravastatin sodium 20 mg tablet, 30
8197K	<i>Pravastatin-GA 40, ED</i> – <b>PRAVASTATIN</b> , pravastatin sodium 40 mg tablet, 30
9239G	<i>Pravastatin-GA 40, ED</i> – <b>PRAVASTATIN</b> , pravastatin sodium 40 mg tablet, 30
8829Q	<i>Pravastatin-GA 80, ED</i> – <b>PRAVASTATIN</b> , pravastatin sodium 80 mg tablet, 30
9240H	<i>Pravastatin-GA 80, ED</i> – <b>PRAVASTATIN</b> , pravastatin sodium 80 mg tablet, 30
9121C	<i>Ramipril-GA, EA</i> – <b>RAMIPRIL</b> , ramipril 2.5 mg capsule, 30
9122D	<i>Ramipril-GA, EA</i> – <b>RAMIPRIL</b> , ramipril 5 mg capsule, 30
8470T	<i>Ramipril-GA, ED</i> – <b>RAMIPRIL</b> , ramipril 10 mg capsule, 30
1944H	<i>APO-Ramipril, TX</i> – <b>RAMIPRIL</b> , ramipril 1.25 mg tablet, 30
1944H	<i>Chem mart Ramipril, CH</i> – <b>RAMIPRIL</b> , ramipril 1.25 mg tablet, 30
1944H	<i>Terry White Chemists Ramipril, TW</i> – <b>RAMIPRIL</b> , ramipril 1.25 mg tablet, 30
8787L	<i>Risperidone Actavis 0.5, ED</i> – <b>RISPERIDONE</b> , risperidone 500 microgram tablet, 60
8869T	<i>Risperidone Actavis 0.5, ED</i> – <b>RISPERIDONE</b> , risperidone 500 microgram tablet, 60
3169T	<i>Risperidone Actavis 1, ED</i> – <b>RISPERIDONE</b> , risperidone 1 mg tablet, 60
8789N	<i>Risperidone Actavis 1, ED</i> – <b>RISPERIDONE</b> , risperidone 1 mg tablet, 60
3170W	<i>Risperidone Actavis 2, ED</i> – <b>RISPERIDONE</b> , risperidone 2 mg tablet, 60
9079W	<i>Risperidone Actavis 2, ED</i> – <b>RISPERIDONE</b> , risperidone 2 mg tablet, 60

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3171X	<i>Risperidone Actavis 3, ED</i> – <b>RISPERIDONE</b> , risperidone 3 mg tablet, 60
2000G	<i>GenRx Salbutamol, GX</i> – <b>SALBUTAMOL</b> , salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules
2001H	<i>GenRx Salbutamol, GX</i> – <b>SALBUTAMOL</b> , salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules
2236Q	<i>GenRx Sertraline, GX</i> – <b>SERTRALINE</b> , sertraline 50 mg tablet, 30
2236Q	<i>Sertraline Actavis, ED</i> – <b>SERTRALINE</b> , sertraline 50 mg tablet, 30
8836C	<i>Sertraline Actavis, ED</i> – <b>SERTRALINE</b> , sertraline 50 mg tablet, 30
2237R	<i>GenRx Sertraline, GX</i> – <b>SERTRALINE</b> , sertraline 100 mg tablet, 30
2237R	<i>Sertraline Actavis, ED</i> – <b>SERTRALINE</b> , sertraline 100 mg tablet, 30
8837D	<i>Sertraline Actavis, ED</i> – <b>SERTRALINE</b> , sertraline 100 mg tablet, 30
1849H	<i>Sumatriptan-GA, ED</i> – <b>SUMATRIPTAN</b> , sumatriptan 50 mg tablet, 4
2110C	<i>Tamoxen 20 mg, EA</i> – <b>TAMOXIFEN</b> , tamoxifen 20 mg tablet, 60
8355R	<i>Telmigen, ED</i> – <b>TELMISARTAN</b> , telmisartan 40 mg tablet, 28
8355R	<i>Telmisartan RBX, RA</i> – <b>TELMISARTAN</b> , telmisartan 40 mg tablet, 28
8356T	<i>Telmigen, ED</i> – <b>TELMISARTAN</b> , telmisartan 80 mg tablet, 28
8356T	<i>Telmisartan RBX, RA</i> – <b>TELMISARTAN</b> , telmisartan 80 mg tablet, 28
8622T	<i>Telmigen HCT 40/12.5, ED</i> – <b>TELMISARTAN + HYDROCHLOROTHIAZIDE</b> , telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28
8623W	<i>Telmigen HCT 80/12.5, ED</i> – <b>TELMISARTAN + HYDROCHLOROTHIAZIDE</b> , telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
9381R	<i>Telmigen HCT 80/25, ED</i> – <b>TELMISARTAN + HYDROCHLOROTHIAZIDE</b> , telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28
8524P	<i>GA Tramadol SR 150mg, ED</i> – <b>TRAMADOL</b> , tramadol hydrochloride 150 mg modified release tablet, 20
3130R	<i>Vancocin CP, AS</i> – <b>VANCOMYCIN</b> , vancomycin 500 mg injection, 1 vial
3131T	<i>Vancocin CP, AS</i> – <b>VANCOMYCIN</b> , vancomycin 500 mg injection, 1 vial
3323X	<i>Vancocin CP, AS</i> – <b>VANCOMYCIN</b> , vancomycin 500 mg injection, 1 vial ( <b>Dental</b> )
8301X	<i>Venla RBX, RA</i> – <b>VENLAFAXINE</b> , venlafaxine 75 mg capsule: modified release, 28

#### **Deletion – Equivalence Indicator**

1211R	<i>Clomid, SW</i> – <b>CLOMIPHENE</b> , clomiphene citrate 50 mg tablet, 10
2420J	<i>Tofranil 10, ZC</i> – <b>IMIPRAMINE</b> , imipramine hydrochloride 10 mg tablet, 50
2421K	<i>Tofranil 25, ZC</i> – <b>IMIPRAMINE</b> , imipramine hydrochloride 25 mg tablet, 50
5012T	<i>Cilicaine V, FM</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL ( <b>Dental</b> )
9143F	<i>Cilicaine V, FM</i> – <b>PHENOXYMETHYLPENICILLIN</b> , phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

## **Alterations**

### **Alteration – Restriction**

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

8408M	<b>BECLOMETHASONE</b> , BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1 ( <i>Qvar 50 Autohaler</i> )
8409N	<b>BECLOMETHASONE</b> , BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1 ( <i>Qvar 100 Autohaler</i> )
2065Q	<b>BUDESONIDE</b> , budesonide 500 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules ( <i>Pulmicort Respules</i> )
2066R	<b>BUDESONIDE</b> , budesonide 1 mg/2 mL inhalation: solution, 30 x 2 mL ampoules ( <i>Pulmicort Respules</i> )
9494Q	<b>CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE</b> , calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g ( <i>Daivobet</i> )
1779P	<b>DANTROLENE</b> , dantrolene sodium 25 mg capsule, 100 ( <i>Dantrium</i> )
1780Q	<b>DANTROLENE</b> , dantrolene sodium 50 mg capsule, 100 ( <i>Dantrium</i> )
8136F	<b>EFORMOTEROL</b> , eformoterol fumarate dihydrate 12 microgram inhalation: powder for, 60 capsules ( <i>Foradile</i> )

8239P	<b>EFORMOTEROL</b> , eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 60 actuations ( <i>Oxis Turbuhaler</i> )
8240Q	<b>EFORMOTEROL</b> , eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations ( <i>Oxis Turbuhaler</i> )
5491B	<b>EPROSARTAN</b> , eprosartan 600 mg tablet, 28 ( <i>Teveten</i> )
8951D	<b>EPROSARTAN</b> , eprosartan 400 mg tablet, 28 ( <i>Teveten</i> )
5134F	<b>INDACATEROL</b> , indacaterol 150 microgram inhalation: powder for, 30 capsules ( <i>Onbrez</i> )
5137J	<b>INDACATEROL</b> , indacaterol 300 microgram inhalation: powder for, 30 capsules ( <i>Onbrez</i> )
1542E	<b>IPRATROPIUM</b> , ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules ( <i>APO-Ipratropium, Aeron 250, Atrovent, Ipratrin</i> )
8238N	<b>IPRATROPIUM</b> , ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules ( <i>APO-Ipratropium, Aeron 500, Atrovent Adult, Ipratrin Adult</i> )
3387G	<b>LINAGLIPTIN</b> , linagliptin 5 mg tablet, 30 ( <i>Trajenta</i> )
10038H	<b>LINAGLIPTIN + METFORMIN</b> , linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Trajentamet</i> )
10044P	<b>LINAGLIPTIN + METFORMIN</b> , linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Trajentamet</i> )
10045Q	<b>LINAGLIPTIN + METFORMIN</b> , linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60 ( <i>Trajentamet</i> )
1571Q	<b>LOPERAMIDE</b> , loperamide hydrochloride 2 mg capsule, 12 ( <i>Gastrex, Gastro-Stop Loperamide, Imodium</i> )
5492C	<b>OLMESARTAN MEDOXOMIL</b> , olmesartan medoxomil 20 mg tablet, 30 ( <i>Olmotec</i> )
5493D	<b>OLMESARTAN MEDOXOMIL</b> , olmesartan medoxomil 40 mg tablet, 30 ( <i>Olmotec</i> )
2000G	<b>SALBUTAMOL</b> , salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules ( <i>APO-Salbutamol, Asmol 2.5 uni-dose, Butamol 2.5, Pharmacor Salbutamol 2.5, Salbutamol Actavis, Salbutamol Sandoz, Ventolin Nebules</i> )
2001H	<b>SALBUTAMOL</b> , salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules ( <i>APO-Salbutamol, Asmol 5 uni-dose, Butamol 5, Pharmacor Salbutamol 5, Salbutamol Actavis, Salbutamol Sandoz, Ventolin Nebules</i> )
8354Q	<b>SALBUTAMOL</b> , salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1 ( <i>Airomir Autohaler</i> )
8141L	<b>SALMETEROL</b> , salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations ( <i>Serevent Accuhaler</i> )
10128C	<b>SAXAGLIPTIN</b> , saxagliptin 2.5 mg tablet, 28 ( <i>Onglyza</i> )
8983T	<b>SAXAGLIPTIN</b> , saxagliptin 5 mg tablet, 28 ( <i>Onglyza</i> )
10048W	<b>SAXAGLIPTIN + METFORMIN</b> , saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56 ( <i>Kombiglyze XR 2.5/1000</i> )
10051B	<b>SAXAGLIPTIN + METFORMIN</b> , saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28 ( <i>Kombiglyze XR 5/1000</i> )
10055F	<b>SAXAGLIPTIN + METFORMIN</b> , saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28 ( <i>Kombiglyze XR 5/500</i> )
9180E	<b>SITAGLIPTIN</b> , sitagliptin 25 mg tablet, 28 ( <i>Januvia</i> )
9181F	<b>SITAGLIPTIN</b> , sitagliptin 50 mg tablet, 28 ( <i>Januvia</i> )
9182G	<b>SITAGLIPTIN</b> , sitagliptin 100 mg tablet, 28 ( <i>Januvia</i> )
10089B	<b>SITAGLIPTIN + METFORMIN</b> , sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 ( <i>Janumet XR</i> )
10090C	<b>SITAGLIPTIN + METFORMIN</b> , sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56 ( <i>Janumet XR</i> )
9449H	<b>SITAGLIPTIN + METFORMIN</b> , sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 ( <i>Janumet</i> )
9450J	<b>SITAGLIPTIN + METFORMIN</b> , sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 ( <i>Janumet</i> )
9451K	<b>SITAGLIPTIN + METFORMIN</b> , sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 ( <i>Janumet</i> )
9479X	<b>SULFADIAZINE SILVER</b> , sulfadiazine silver 1% cream, 50 g ( <i>Flamazine</i> )
8626B	<b>TIOTROPIUM</b> , tiotropium 18 microgram inhalation: powder for, 30 capsules ( <i>Spiriva</i> )
3415R	<b>VILDAGLIPTIN</b> , vildagliptin 50 mg tablet, 60 ( <i>Galvus</i> )
5474D	<b>VILDAGLIPTIN + METFORMIN</b> , vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 ( <i>Galvumet 50/500</i> )

5475E	<b>VILDAGLIPTIN + METFORMIN</b> , vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 ( <i>Galvumet 50/850</i> )		
5476F	<b>VILDAGLIPTIN + METFORMIN</b> , vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 ( <i>Galvumet 50/1000</i> )		

**Alteration – Restriction Level**

		From	To
1571Q	<b>LOPERAMIDE</b> , loperamide hydrochloride 2 mg capsule, 12 ( <i>Gastrex, Gastro-Stop Loperamide, Imodium</i> )	unrestricted	streamlined

**Alteration – Manufacturer Code**

		From	To
5296R	<i>Riamet 20mg/120mg Dispersible</i> – <b>ARTEMETHER + LUMEFANTRINE</b> , artemether 20 mg + lumefantrine 120 mg dispersible tablet, 18	NV	SZ
9498X	<i>Riamet</i> – <b>ARTEMETHER + LUMEFANTRINE</b> , artemether 20 mg + lumefantrine 120 mg tablet, 24	NV	SZ
1443Y	<i>Parlodel</i> – <b>BROMOCRIPTINE</b> , bromocriptine 2.5 mg tablet, 30	NV	SZ
1444B	<i>Parlodel</i> – <b>BROMOCRIPTINE</b> , bromocriptine 2.5 mg tablet, 30	NV	SZ
1561E	<i>Anafranil 25</i> – <b>CLOMIPRAMINE</b> , clomipramine hydrochloride 25 mg tablet, 50	NV	SZ
8136F	<i>Foradile</i> – <b>EFORMOTEROL</b> , eformoterol fumarate dihydrate 12 microgram inhalation: powder for, 60 capsules	NV	SZ
8092X	<i>Famvir</i> – <b>FAMCICLOVIR</b> , famciclovir 125 mg tablet, 40	NV	HX
2274Q	<i>Famvir</i> – <b>FAMCICLOVIR</b> , famciclovir 250 mg tablet, 20	NV	HX
8002E	<i>Famvir</i> – <b>FAMCICLOVIR</b> , famciclovir 250 mg tablet, 21	NV	HX
8217L	<i>Famvir</i> – <b>FAMCICLOVIR</b> , famciclovir 250 mg tablet, 56	NV	HX
8896F	<i>Famvir</i> – <b>FAMCICLOVIR</b> , famciclovir 500 mg tablet, 56	NV	HX
8897G	<i>Famvir</i> – <b>FAMCICLOVIR</b> , famciclovir 500 mg tablet, 30	NV	HX
1515R	<i>Transiderm-Nitro 25</i> – <b>GLYCERYL TRINITRATE</b> , glyceryl trinitrate 5 mg/24 hours patch, 30	NV	SZ
1516T	<i>Transiderm-Nitro 50</i> – <b>GLYCERYL TRINITRATE</b> , glyceryl trinitrate 10 mg/24 hours patch, 30	NV	SZ
8425K	<i>Estalis sequi 50/140</i> – <b>NORETHISTERONE ACETATE + OESTRADIOL (&amp; OESTRADIOL</b> , oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 1 pack	NV	SZ
8426L	<i>Estalis sequi 50/250</i> – <b>NORETHISTERONE ACETATE + OESTRADIOL (&amp; OESTRADIOL</b> , oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 1 pack	NV	SZ
8761D	<i>Estradot 25</i> – <b>OESTRADIOL</b> , oestradiol 25 microgram/24 hours patch, 8	NV	SZ
8762E	<i>Estradot 37.5</i> – <b>OESTRADIOL</b> , oestradiol 37.5 microgram/24 hours patch, 8	NV	SZ
8763F	<i>Estradot 50</i> – <b>OESTRADIOL</b> , oestradiol 50 microgram/24 hours patch, 8	NV	SZ
8764G	<i>Estradot 75</i> – <b>OESTRADIOL</b> , oestradiol 75 microgram/24 hours patch, 8	NV	SZ
8765H	<i>Estradot 100</i> – <b>OESTRADIOL</b> , oestradiol 100 microgram/24 hours patch, 8	NV	SZ
8428N	<i>Estalis continuous 50/250</i> – <b>OESTRADIOL + NORETHISTERONE ACETATE</b> , oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8	NV	SZ
8427M	<i>Estalis continuous 50/140</i> – <b>OESTRADIOL + NORETHISTERONE ACETATE</b> , oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8	NV	SZ
9288W	<i>Aclasta</i> – <b>ZOLEDRONIC ACID</b> , zoledronic acid 5 mg/100 mL injection, 100 mL vial	NV	HX
9350D	<i>Aclasta</i> – <b>ZOLEDRONIC ACID</b> , zoledronic acid 5 mg/100 mL injection, 100 mL vial	NV	HX

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## Advance Notices

1 October 2016

### Deletion – Brand

8118G	Chem mart Alprazolam, CH – <b>ALPRAZOLAM</b> , alprazolam 2 mg tablet, 50
8118G	Terry White Chemists Alprazolam, TW – <b>ALPRAZOLAM</b> , alprazolam 2 mg tablet, 50
8296P	Candesartan RBX, RA – <b>CANDESARTAN</b> , candesartan cilexetil 8 mg tablet, 30
9314F	Candesartan HCTZ RBX 32/12.5, RA – <b>CANDESARTAN + HYDROCHLOROTHIAZIDE</b> , candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
8255L	Dilatrend 3.125, RO – <b>CARVEDILOL</b> , carvedilol 3.125 mg tablet, 30
8439E	Celecoxib Actavis, ED – <b>CELECOXIB</b> , celecoxib 100 mg capsule, 60
8440F	Celecoxib Actavis, ED – <b>CELECOXIB</b> , celecoxib 200 mg capsule, 30
1299J	Diclofenac-GA, ED – <b>DICLOFENAC</b> , diclofenac sodium 25 mg tablet: enteric, 50
1300K	Diclofenac-GA, ED – <b>DICLOFENAC</b> , diclofenac sodium 50 mg tablet: enteric, 50
5076E	Diclofenac-GA, ED – <b>DICLOFENAC</b> , diclofenac sodium 25 mg tablet: enteric, 50 ( <b>Dental</b> )
5077F	Diclofenac-GA, ED – <b>DICLOFENAC</b> , diclofenac sodium 50 mg tablet: enteric, 50 ( <b>Dental</b> )
2924X	Rythmodan, SW – <b>DISOPYRAMIDE</b> , disopyramide 150 mg capsule, 100
2711Q	Doxy-50, ED – <b>DOXYCYCLINE</b> , doxycycline 50 mg tablet, 25
1834M	Gantin, EA – <b>GABAPENTIN</b> , gabapentin 300 mg capsule, 100
1835N	Gantin, EA – <b>GABAPENTIN</b> , gabapentin 400 mg capsule, 100
8389M	Gantin, ED – <b>GABAPENTIN</b> , gabapentin 800 mg tablet, 100
8182P	Roferon-A, RO – <b>INTERFERON ALFA-2A</b> , interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe
8551C	Roferon-A, RO – <b>INTERFERON ALFA-2A</b> , interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe
8245Y	Lezole, ED – <b>LETROZOLE</b> , letrozole 2.5 mg tablet, 30
2734X	Megace, QA – <b>MEGESTROL</b> , megestrol acetate 160 mg tablet, 30
8887R	Melox 7.5, EA – <b>MELOXICAM</b> , meloxicam 7.5 mg capsule, 30
8888T	Melox 15, EA – <b>MELOXICAM</b> , meloxicam 15 mg capsule, 30
1821W	DBL Metronidazole Intravenous Infusion, HH – <b>METRONIDAZOLE</b> , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags
1832K	DBL Metronidazole Intravenous Infusion, HH – <b>METRONIDAZOLE</b> , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags ( <b>Dental</b> )
9006B	Chem mart Perindopril Arginine, CH – <b>PERINDOPRIL</b> , perindopril arginine 2.5 mg tablet, 30
9006B	Terry White Chemists Perindopril Arginine, TW – <b>PERINDOPRIL</b> , perindopril arginine 2.5 mg tablet, 30
9006B	PERINDO ARG 2.5mg, TR – <b>PERINDOPRIL</b> , perindopril arginine 2.5 mg tablet, 30
9006B	IDAPREX ARG 2.5mg, TZ – <b>PERINDOPRIL</b> , perindopril arginine 2.5 mg tablet, 30
9006B	Blooms the Chemist Perindopril Arginine, IB – <b>PERINDOPRIL</b> , perindopril arginine 2.5 mg tablet, 30
9007C	Chem mart Perindopril Arginine, CH – <b>PERINDOPRIL</b> , perindopril arginine 5 mg tablet, 30
9007C	Terry White Chemists Perindopril Arginine, TW – <b>PERINDOPRIL</b> , perindopril arginine 5 mg tablet, 30
9007C	PERINDO ARG 5mg, TR – <b>PERINDOPRIL</b> , perindopril arginine 5 mg tablet, 30
9007C	IDAPREX ARG 5mg, TZ – <b>PERINDOPRIL</b> , perindopril arginine 5 mg tablet, 30
9007C	Blooms the Chemist Perindopril Arginine, IB – <b>PERINDOPRIL</b> , perindopril arginine 5 mg tablet, 30
9008D	Chem mart Perindopril Arginine, CH – <b>PERINDOPRIL</b> , perindopril arginine 10 mg tablet, 30
9008D	Terry White Chemists Perindopril Arginine, TW – <b>PERINDOPRIL</b> , perindopril arginine 10 mg tablet, 30
9008D	PERINDO ARG 10mg, TR – <b>PERINDOPRIL</b> , perindopril arginine 10 mg tablet, 30
9008D	IDAPREX ARG 10mg, TZ – <b>PERINDOPRIL</b> , perindopril arginine 10 mg tablet, 30

9008D *Blooms the Chemist Perindopril Arginine, IB – PERINDOPRIL*, perindopril arginine 10 mg tablet, 30

9346X *Chem mart Perindopril Arginine/Amlodipine 5/5, CH – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

9346X *Terry White Chemists Perindopril Arginine/Amlodipine 5/5, TW – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

9346X *Blooms the Chemist Perindopril Arginine/Amlodipine 5/5, IB – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

9346X *Deflectum 5/5, TZ – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

9346X *Dynoval 5/5, TR – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

9347Y *Chem mart Perindopril Arginine/Amlodipine 5/10, CH – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

9347Y *Terry White Chemists Perindopril Arginine/Amlodipine 5/10, TW – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

9347Y *Blooms the Chemist Perindopril Arginine/Amlodipine 5/10, IB – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

9347Y *Deflectum 5/10, TZ – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

9347Y *Dynoval 5/10, TR – PERINDOPRIL + AMLODIPINE*, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

9348B *Chem mart Perindopril Arginine/Amlodipine 10/5, CH – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

9348B *Terry White Chemists Perindopril Arginine/Amlodipine 10/5, TW – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

9348B *Blooms the Chemist Perindopril Arginine/Amlodipine 10/5, IB – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

9348B *Deflectum 10/5, TZ – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

9348B *Dynoval 10/5, TR – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

9349C *Chem mart Perindopril Arginine/Amlodipine 10/10, CH – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

9349C *Terry White Chemists Perindopril Arginine/Amlodipine 10/10, TW – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

9349C *Blooms the Chemist Perindopril Arginine/Amlodipine 10/10, IB – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

9349C *Deflectum 10/10, TZ – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

9349C *Dynoval 10/10, TR – PERINDOPRIL + AMLODIPINE*, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

2845R *Perindo ARG Combi 5mg/1.25mg, TR – PERINDOPRIL + INDAPAMIDE*, perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

2845R *Idaprex ARG Combi 5mg/1.25mg, TZ – PERINDOPRIL + INDAPAMIDE*, perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

1897W *Terry White Chemists Piroxicam, TW – PIROXICAM*, piroxicam 10 mg capsule, 50

1897W *Chem mart Piroxicam, CH – PIROXICAM*, piroxicam 10 mg capsule, 50

5203W *Terry White Chemists Piroxicam, TW – PIROXICAM*, piroxicam 10 mg capsule, 50 (Dental)

5203W *Chem mart Piroxicam, CH – PIROXICAM*, piroxicam 10 mg capsule, 50 (Dental)

8580N *Quetiapine AN, EA – QUETIAPINE*, quetiapine 300 mg tablet, 60

1968N *Aquinafil, EA – QUINAPRIL*, quinapril 5 mg tablet, 30

1969P *Aquinafil, EA – QUINAPRIL*, quinapril 10 mg tablet, 30

1970Q *Aquinafil, EA – QUINAPRIL*, quinapril 20 mg tablet, 30

2590H *Rosuvastatin Actavis 5, ED – ROSUVASTATIN*, rosuvastatin 5 mg tablet, 30

2606E *Rosuvastatin Actavis 5, ED – ROSUVASTATIN*, rosuvastatin 5 mg tablet, 30

3402C *Rosuvastatin Actavis 5, ED – ROSUVASTATIN*, rosuvastatin 5 mg tablet, 30

3402C *Rosuvastatin AN, EA – ROSUVASTATIN*, rosuvastatin 5 mg tablet, 30

3403D	<i>Rosuvastatin AN, EA</i> – <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30
3404E	<i>Rosuvastatin AN, EA</i> – <b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30
3405F	<i>Rosuvastatin AN, EA</i> – <b>ROSUVASTATIN</b> , rosuvastatin 40 mg tablet, 30
9042X	<i>Rosuvastatin Actavis 5, ED</i> – <b>ROSUVASTATIN</b> , rosuvastatin 5 mg tablet, 30
9042X	<i>Rosuvastatin AN, EA</i> – <b>ROSUVASTATIN</b> , rosuvastatin 5 mg tablet, 30
9043Y	<i>Rosuvastatin AN, EA</i> – <b>ROSUVASTATIN</b> , rosuvastatin 10 mg tablet, 30
9044B	<i>Rosuvastatin AN, EA</i> – <b>ROSUVASTATIN</b> , rosuvastatin 20 mg tablet, 30
9045C	<i>Rosuvastatin AN, EA</i> – <b>ROSUVASTATIN</b> , rosuvastatin 40 mg tablet, 30
2236Q	<i>Xydep 50, EF</i> – <b>SERTRALINE</b> , sertraline 50 mg tablet, 30
2237R	<i>Xydep 100, EF</i> – <b>SERTRALINE</b> , sertraline 100 mg tablet, 30
8836C	<i>Xydep 50, EF</i> – <b>SERTRALINE</b> , sertraline 50 mg tablet, 30
8837D	<i>Xydep 100, EF</i> – <b>SERTRALINE</b> , sertraline 100 mg tablet, 30
2285G	<i>Terbinafine Actavis, ED</i> – <b>TERBINAFINE</b> , terbinafine 250 mg tablet, 42
2804N	<i>Terbinafine Actavis, ED</i> – <b>TERBINAFINE</b> , terbinafine 250 mg tablet, 42
8301X	<i>Venlafaxine Actavis XR, ED</i> – <b>VENLAFAXINE</b> , venlafaxine 75 mg capsule: modified release, 28
8302Y	<i>Venlafaxine Actavis XR, ED</i> – <b>VENLAFAXINE</b> , venlafaxine 150 mg capsule: modified release, 28
8868R	<i>Venlafaxine Actavis XR, ED</i> – <b>VENLAFAXINE</b> , venlafaxine 37.5 mg capsule: modified release, 28

### 1 December 2016

#### Deletion – Brand

2014B	<i>Gaviscon P, RC</i> – <b>ALGINATE SODIUM + CALCIUM CARBONATE + BICARBONATE</b> , alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL
1397M	<i>Erythrocin-I.V., ZC</i> – <b>ERYTHROMYCIN LACTOBIONATE</b> , erythromycin (as lactobionate) 1 g injection, 1 vial
5088T	<i>Erythrocin-I.V., ZC</i> – <b>ERYTHROMYCIN LACTOBIONATE</b> , erythromycin (as lactobionate) 1 g injection, 1 vial <b>(Dental)</b>
1182F	<i>Monopril, BQ</i> – <b>FOSINOPRIL</b> , fosinopril sodium 10 mg tablet, 30
1183G	<i>Monopril, BQ</i> – <b>FOSINOPRIL</b> , fosinopril sodium 20 mg tablet, 30
8401E	<i>Monoplus 20/12.5, BQ</i> – <b>FOSINOPRIL + HYDROCHLOROTHIAZIDE</b> , fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30
10063P	<i>Isopto Homatropine, AQ</i> – <b>HOMATROPINE</b> , homatropine hydrobromide 2% eye drops, 15 mL <b>(Optometrical)</b>
2541R	<i>Isopto Homatropine, AQ</i> – <b>HOMATROPINE</b> , homatropine hydrobromide 2% eye drops, 15 mL

## Palliative Care

### Advance Notices

#### 1 October 2016

#### Deletion – Brand

5361E	<i>Diclofenac-GA, ED</i> – <b>DICLOFENAC</b> , diclofenac sodium 25 mg tablet: enteric, 50
5362F	<i>Diclofenac-GA, ED</i> – <b>DICLOFENAC</b> , diclofenac sodium 50 mg tablet: enteric, 50

## Highly Specialised Drugs Program (Private Hospital)

### Additions

#### Addition – Item

10880P	<b>PASIREOTIDE</b> , pasireotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack ( <i>Signifor LAR</i> )
10884W	<b>PASIREOTIDE</b> , pasireotide 40 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack ( <i>Signifor LAR</i> )
10887B	<b>PASIREOTIDE</b> , pasireotide 60 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack ( <i>Signifor LAR</i> )

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## Alterations

### Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

6195C **RIFABUTIN**, rifabutin 150 mg capsule, 30 (*Mycobutin*)

## Advance Notices

1 October 2016

### Deletion – Brand

6211X *Roferon-A, RO* – **INTERFERON ALFA-2A**, interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe

## Highly Specialised Drugs Program (Public Hospital)

### Additions

#### Addition – Item

10886Y **PASIREOTIDE**, pasireotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*)

10883T **PASIREOTIDE**, pasireotide 40 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*)

10882R **PASIREOTIDE**, pasireotide 60 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (*Signifor LAR*)

### Alterations

#### Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

9541E **RIFABUTIN**, rifabutin 150 mg capsule, 30 (*Mycobutin*)

## Advance Notices

1 October 2016

### Deletion – Brand

5760E *Roferon-A, RO* – **INTERFERON ALFA-2A**, interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe

## Highly Specialised Drugs Program (Community Access)

### Advance Notices

1 October 2016

#### Deletion – Brand

10371W *Roferon-A, RO* – **INTERFERON ALFA-2A**, interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe

10304H *Nevipin, EA* – **NEVIRAPINE**, nevirapine 200 mg tablet, 60

## Repatriation Pharmaceutical Benefits

### Alterations

#### Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

4348W **MUPIROCIN**, mupirocin 2% cream, 15 g (*Bactroban*)

4350Y **MUPIROCIN**, mupirocin 2% ointment, 15 g (*Bactroban*)

4390C **PODOPHYLLOTOXIN**, podophyllotoxin 0.15% cream, 5 g (*Wartec Cream*)

#### Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
4046Y	<i>Solaraze 3% Gel</i> – <b>DICLOFENAC</b> , diclofenac sodium 3% gel, 25 g	CS	FK

# General Pharmaceutical Benefits

## ▪ BECLOMETHASONE

### Restricted benefit

Asthma

### Clinical criteria:

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

### **BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1**

8409N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	37.58	38.30	Qvar 100 Autohaler [IA]

### **BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1**

8408M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	28.28	29.47	Qvar 50 Autohaler [IA]

## ▪ BUDESONIDE

### Authority required (STREAMLINED)

**6340**

Severe chronic asthma

### Clinical criteria:

- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

### **budesonide 1 mg/2 mL inhalation: solution, 30 x 2 mL ampoules**

2066R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	46.74	38.30	Pulmicort Respules [AP]

### **budesonide 500 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules**

2065Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	5	..	36.54	37.73	Pulmicort Respules [AP]

## ▪ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

### Restricted benefit

Chronic stable plaque type psoriasis vulgaris

### Clinical criteria:

- The condition must be inadequately controlled by calcipotriol; OR
- The condition must be inadequately controlled by potent topical corticosteroid monotherapy.

### **calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g**

9494Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	1	..	41.53	38.30	Daivobet [LO]

## ▪ DANTROLENE

### Restricted benefit

Chronic spasticity

### dantrolene sodium 25 mg capsule, 100

1779P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	75.14	38.30	Dantrium [PF]

### dantrolene sodium 50 mg capsule, 100

1780Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	2	..	75.67	38.30	Dantrium [PF]

## ■ EFORMOTEROL

### Restricted benefit

Asthma

### Clinical criteria:

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

### eformoterol fumarate dihydrate 12 microgram inhalation: powder for, 60 capsules

8136F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	36.10	37.29	Foradile [SZ]

### eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations

8240Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	35.35	36.54	Oxis Turbuhaler [AP]

### eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 60 actuations

8239P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	27.05	28.24	Oxis Turbuhaler [AP]

## ■ EPROSARTAN

### Authority required

Adverse effects occurring with all of the base-priced drugs

### Authority required

Drug interactions occurring with all of the base-priced drugs

### Authority required

Drug interactions expected to occur with all of the base-priced drugs

### Authority required

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

### eprosartan 400 mg tablet, 28

8951D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*29.92	31.11	Teveten [GO]

### eprosartan 600 mg tablet, 28

5491B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	29.55	30.74	Teveten [GO]

## ■ EXENATIDE

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.

### Authority required (STREAMLINED)

**6354**

Diabetes mellitus type 2

### Clinical criteria:

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR
- Patient must not have tolerated a combination of metformin and a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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.

**Authority required (STREAMLINED)**

**6339**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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.

**exenatide 2 mg/dose injection: modified release, 4 injection devices**

10888C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	130.38	38.30	Bydureon [AP]

▪ **INDACATEROL**

**Note** This drug is not PBS-subsidised for the treatment of asthma.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**indacaterol 150 microgram inhalation: powder for, 30 capsules**

5134F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	61.44	38.30	Onbrez [NV]

**indacaterol 300 microgram inhalation: powder for, 30 capsules**

5137J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	61.44	38.30	Onbrez [NV]

▪ **IPRATROPIUM**

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**Restricted benefit**

Chronic obstructive pulmonary disease (COPD)

**Clinical criteria:**

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

**ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules**

1542E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*29.28	30.47	<sup>a</sup> Aeron 250 [QA]	<sup>a</sup> APO-Ipratropium [TX]
						<sup>a</sup> Ipratrin [AF]	
			<sup>b</sup> 0.50	*29.78	30.47	<sup>a</sup> Atrovent [BY]	

**ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules**

8238N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*32.68	33.87	<sup>a</sup> Aeron 500 [QA]	<sup>a</sup> APO-Ipratropium [TX]
						<sup>a</sup> Ipratrin Adult [AF]	

▪ **LINAGLIPTIN**

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6346**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; 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 either metformin or a sulfonylurea.

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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**6363**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**linagliptin 5 mg tablet, 30**

3387G



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	61.64	38.30	Trajenta [BY]

▪ **LINAGLIPTIN + METFORMIN**

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

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6333**

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)**

**6336**

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.

**Authority required (STREAMLINED)**

**6344**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60**

10044P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	65.13	38.30	Trajentamet [BY]

**linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60**

10038H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	63.44	38.30	Trajentamet [BY]

**linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60**

10045Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	64.64	38.30	Trajentamet [BY]

## ■ LOPERAMIDE

### Authority required (STREAMLINED)

6364

Diarrhoea

### Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

### loperamide hydrochloride 2 mg capsule, 12

1571Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.05	13.24	<sup>a</sup> Gastrex [CR]	<sup>a</sup> Gastro-Stop Loperamide [AS]
			<sup>B</sup> 0.65	12.70	13.24	<sup>a</sup> Imodium [JT]	

## ■ LOPERAMIDE

### Authority required

Diarrhoea

### loperamide hydrochloride 2 mg capsule, 12

10889D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	..	..	*18.02	19.21	<sup>a</sup> Gastrex [CR]	<sup>a</sup> Gastro-Stop Loperamide [AS]
			<sup>B</sup> 3.25	*21.27	19.21	<sup>a</sup> Imodium [JT]	

## ■ OLMESARTAN MEDOXOMIL

### Authority required

Adverse effects occurring with all of the base-priced drugs

### Authority required

Drug interactions occurring with all of the base-priced drugs

### Authority required

Drug interactions expected to occur with all of the base-priced drugs

### Authority required

Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

### olmesartan medoxomil 20 mg tablet, 30

5492C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.05	23.24	Olmotec [MK]

### olmesartan medoxomil 40 mg tablet, 30

5493D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	31.01	32.20	Olmotec [MK]

## ■ SALBUTAMOL

### Restricted benefit

Bronchospasm

### Clinical criteria:

- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

### salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1

8354Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*38.54	38.30	Airomir Autohaler [IA]

## ■ SALBUTAMOL

### Restricted benefit

Asthma

### Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

### Clinical criteria:

- Patient must be unable to use this drug delivered from an oral pressurised inhalation device via a spacer.

### salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

2000G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.56	19.75	<sup>a</sup> APO-Salbutamol [TX]	<sup>a</sup> Butamol 2.5 [QA]
						<sup>a</sup> Pharmacor Salbutamol 2.5 [CR]	<sup>a</sup> Salbutamol Actavis [EA]
						<sup>a</sup> Salbutamol Sandoz [SZ]	
			<sup>B</sup> 0.50	*19.06	19.75	<sup>a</sup> Asmol 2.5 uni-dose [AF]	

<sup>B</sup>1.04 \*19.60 19.75 <sup>a</sup> Ventolin Nebules [GK]

**salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules**

2001H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*18.98	20.17	<sup>a</sup> APO-Salbutamol [TX] <sup>a</sup> Pharmacor Salbutamol 5 [CR] <sup>a</sup> Salbutamol Sandoz [SZ]	<sup>a</sup> Butamol 5 [QA] <sup>a</sup> Salbutamol Actavis [EA]
			<sup>B</sup> 0.50	*19.48	20.17	<sup>a</sup> Asmol 5 uni-dose [AF]	
			<sup>B</sup> 1.00	*19.98	20.17	<sup>a</sup> Ventolin Nebules [GK]	

▪ **SALMETEROL**

**Restricted benefit**

Asthma

**Clinical criteria:**

- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

**salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations**

8141L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	±1	5	..	36.10	37.29	Serevent Accuhaler [GK]

▪ **SAXAGLIPTIN**

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6346**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; 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 either metformin or a sulfonylurea. 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**6363**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

### saxagliptin 2.5 mg tablet, 28

10128C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.23	38.30	Onglyza [AP]

### saxagliptin 5 mg tablet, 28

8983T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.23	38.30	Onglyza [AP]

## ■ SAXAGLIPTIN + METFORMIN

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

### **Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

#### Authority required (STREAMLINED)

#### **6333**

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)

#### **6335**

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.

#### Authority required (STREAMLINED)

#### **6344**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

### saxagliptin 2.5 mg + metformin hydrochloride 1 g modified release tablet, 56

10048W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.48	38.30	Kombiglyze XR 2.5/1000 [AP]

### saxagliptin 5 mg + metformin hydrochloride 1 g modified release tablet, 28

10051B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.91	38.30	Kombiglyze XR 5/1000 [AP]

### saxagliptin 5 mg + metformin hydrochloride 500 mg modified release tablet, 28

10055F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.07	38.30	Kombiglyze XR 5/500 [AP]

## ■ SITAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

##### **6346**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; 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 either metformin or a sulfonylurea. 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

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

##### **6363**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

### sitagliptin 100 mg tablet, 28

9182G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.85	38.30	Januvia [MK]

### sitagliptin 25 mg tablet, 28

9180E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.85	38.30	Januvia [MK]

### sitagliptin 50 mg tablet, 28

9181F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	55.85	38.30	Januvia [MK]

## ■ SITAGLIPTIN + METFORMIN

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

### **Note** Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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

##### **6333**

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)**

##### **6334**

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 sitagliptin.

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

##### **6344**

Diabetes mellitus type 2

#### **Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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 clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

### sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

10089B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	57.52	38.30	Janumet XR [MK]

### sitagliptin 50 mg + metformin hydrochloride 1 g modified release tablet, 56

10090C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.09	38.30	Janumet XR [MK]

### sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

9451K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	59.09	38.30	Janumet [MK]

### sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

9449H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	57.52	38.30	Janumet [MK]

### sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

9450J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	58.64	38.30	Janumet [MK]

## ▪ SULFADIAZINE SILVER

### Restricted benefit

Infection

Treatment Phase: Prevention and treatment

### **Clinical criteria:**

- The condition must be in partial or full skin thickness loss due to burns; OR
- The condition must be in partial or full skin thickness loss due to epidermolysis bullosa.

### Restricted benefit

Stasis ulcers

### sulfadiazine silver 1% cream, 50 g

9479X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	‡1	..	..	21.09	22.28	Flamazine [SN]

## ▪ TIOTROPIUM

### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

### tiotropium 18 microgram inhalation: powder for, 30 capsules

8626B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	5	..	58.89	38.30	Spiriva [BY]

## ▪ VILDAGLIPTIN

**Note** This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

### **Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6346**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin; OR
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; 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 either metformin or a sulfonylurea.

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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Authority required (STREAMLINED)**

**6363**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with metformin, **AND**
- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**vildagliptin 50 mg tablet, 60**

3415R



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	59.08	38.30	Galvus [NV]

**■ VILDAGLIPTIN + METFORMIN**

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

**Note Continuing Therapy Only:**

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

**Authority required (STREAMLINED)**

**6333**

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)**

**6357**

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 vildagliptin.

**Authority required (STREAMLINED)**

**6344**

Diabetes mellitus type 2

**Clinical criteria:**

- The treatment must be in combination with a sulfonylurea, **AND**
- Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; 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 prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy.

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 gliptin, a glitazone, a glucagon-like peptide-1 or an 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 or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

**vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60**

5476F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	59.77	38.30	Galvumet 50/1000 [NV]

**vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60**

5474D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	58.08	38.30	Galvumet 50/500 [NV]

**vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60**

5475E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	59.29	38.30	Galvumet 50/850 [NV]

# Highly Specialised Drugs Program (Private Hospital)

## ▪ PASIREOTIDE

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

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### Authority required

Acromegaly

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 2.5 micrograms per litre, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) level greater than 1.3 times the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information.

#### **Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment develops during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control is defined as:

- 1) Growth hormone level is greater than 2.5 mcg/mL; and
- 2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) a signed patient acknowledgment; and
- d) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- e) a recent copy of GH and IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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### Authority required

Acromegaly

Treatment Phase: Grandfathering treatment

#### **Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016.

#### **Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) a signed patient acknowledgment; and
- d) in a patient who has previously been treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Acromegaly

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

#### **Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **pasireotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10880P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.02	Signifor LAR [NV]

#### **pasireotide 40 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10884W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.02	Signifor LAR [NV]

#### **pasireotide 60 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10887B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7847.02	Signifor LAR [NV]

#### **▪ RIFABUTIN**

##### **Authority required**

Mycobacterium avium complex infection

##### **Clinical criteria:**

- Patient must be human immunodeficiency virus (HIV) positive.

##### **Authority required**

Mycobacterium avium complex infection

##### **Clinical criteria:**

- The treatment must be for prophylaxis, **AND**

- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**rifabutin 150 mg capsule, 30**

6195C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*646.62	Mycobutin [PF]

# Highly Specialised Drugs Program (Public Hospital)

## ▪ PASIREOTIDE

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

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### Authority required

Acromegaly

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 2.5 micrograms per litre, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) level greater than 1.3 times the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information.

#### **Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment develops during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control is defined as:

- 1) Growth hormone level is greater than 2.5 mcg/mL; and
- 2) IGF-1 level is greater than 1.3 times the age- and sex-adjusted ULN

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) a signed patient acknowledgment; and
- d) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- e) a recent copy of GH and IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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### Authority required

Acromegaly

Treatment Phase: Grandfathering treatment

#### **Clinical criteria:**

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016.

#### **Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) a signed patient acknowledgment; and
- d) in a patient who has previously been treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Acromegaly

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

#### **Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 2.5 mcg/L; and
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **pasireotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10886Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

#### **pasireotide 40 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10883T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

#### **pasireotide 60 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10882R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7800.00	Signifor LAR [NV]

#### **▪ RIFABUTIN**

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

**6350**

Mycobacterium avium complex infection

##### **Clinical criteria:**

- Patient must be human immunodeficiency virus (HIV) positive.

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

**6356**

Mycobacterium avium complex infection

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**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**rifabutin 150 mg capsule, 30**

9541E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*615.00	Mycobutin [PF]

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# Repatriation Pharmaceutical Benefits Scheme

## ▪ MUPIROCIN

### Restricted benefit

Secondarily infected traumatic skin lesions

#### **mupirocin 2% cream, 15 g**

4348W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.98	6.20	Bactroban [GK]

#### **mupirocin 2% ointment, 15 g**

4350Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	19.98	6.20	Bactroban [GK]

## ▪ PODOPHYLLOTOXIN

### Authority required

Ano-genital warts

#### **podophyllotoxin 0.15% cream, 5 g**

4390C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	52.30	6.20	Wartec Cream [GK]