Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

SUMMARY OF CHANGES

EFFECTIVE 1 JANUARY 2007 – 31 JANUARY 2007

PHARMACEUTICAL BENEFITS

This Schedule will take effect on 1 January 2007 and all previous issues are cancelled.
New Schedules will take effect monthly on the first day of each month.

Internet

The Schedule of Pharmaceutical Benefits is also available on the Internet. The address of the Schedule is www.pbs.gov.au

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 January 2007 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$5.15
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$7.19
Additional Fees (for safety net prices):	Ready-prepared	$0.99
	Extemporaneously-prepared	$1.38
Patient Co-payments:	General	$30.70
	Concessional	$4.90
Safety Net Thresholds:	General	$1059.00
	Concessional	$274.40
Safety Net Card Issue Fee:		$7.72

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

8682Y **Glucose Indicator — Blood,** electrode strips, 50 *(MWD Pen Sensor Strips)*
9063B **Glucose Indicator — Blood,** electrode strips, 50 *(Omnitest Plus)*

Additions — Brands

1471K *Fluconazole Hexal, HX* — **Fluconazole,** capsule 50 mg
1472L *Fluconazole Hexal, HX* — **Fluconazole,** capsule 100 mg
1475P *Fluconazole Hexal, HX* — **Fluconazole,** capsule 200 mg
8539K *MX* — **Oxaliplatin,** powder for I.V. infusion 50 mg
8540L *MX* — **Oxaliplatin,** powder for I.V. infusion 100 mg

BIOEQUIVALENCE INDICATORS

The bioequivalence indicator (a) has been added to the following items:

8847P **Oxaliplatin,** solution concentrate for I.V. infusion 50 mg in 10 mL *(Eloxatin)*
8848Q **Oxaliplatin,** solution concentrate for I.V. infusion 100 mg in 20 mL *(Eloxatin)*

DELETIONS

Deletions — Items

8635L **Moxifloxacin Hydrochloride,** solution for I.V. infusion 400 mg (base) in 250 mL *(Avelox)*
8636M **Moxifloxacin Hydrochloride,** tablet 400 mg (base) *(Avelox)*

ALTERATIONS

Restriction Changes (see under 'RESTRICTIONS' below for full details)

8757X **Ezetimibe,** tablet 10 mg *(Ezetrol)*
8881K **Ezetimibe with Simvastatin,** tablet 10 mg-40 mg *(Vytorin)*
8882L **Ezetimibe with Simvastatin,** tablet 10 mg-80 mg *(Vytorin)*

Alterations — Notes (see under 'NOTES' below for full details)

Notes have been added in respect of the following:

Oxaliplatin

Notes have been deleted in respect of the following:

Rosuvastatin Calcium

Alterations —Item Description

From:
2315W **Bleomycin Sulfate,** powder for injection 15,000 i.u.
To:
2315W **Bleomycin Sulfate,** powder for injection 15,000 i.u. (solvent required)
(code 6896Y applies to above item with approved solvent)
From:
8315P **Cefepime,** powder for injection 1 g
To:
8315P **Cefepime,** powder for injection 1 g (solvent required)
(code 7079N applies to above item with approved solvent)
From:
8316Q **Cefepime,** powder for injection 2 g
To:
8316Q **Cefepime,** powder for injection 2 g (solvent required)
(code 7085X applies to above item with approved solvent)
From:
1079T **Cyclophosphamide,** powder for injection 500 mg
To:
1079T **Cyclophosphamide,** powder for injection 500 mg (solvent required)
(code 6704W applies to above item with approved solvent)
From:
1080W **Cyclophosphamide,** powder for injection 1 g
To:
1080W **Cyclophosphamide,** powder for injection 1 g (solvent required)
(code 6710E applies to above item with approved solvent)
From:
1031G **Cyclophosphamide,** powder for injection 2 g
To:
1031G **Cyclophosphamide,** powder for injection 2 g (solvent required)
(code 7055H applies to above item with approved solvent)
From:
2179Q **Ticarcillin with Clavulanic Acid,** powder for injection 3 g-100 mg
To:
2179Q **Ticarcillin with Clavulanic Acid,** powder for injection 3 g-100 mg (solvent required)
(code 6884H applies to above item with approved solvent)
From:
5230G **Ticarcillin with Clavulanic Acid,** powder for injection 3 g-100 mg **(Dental)**
To:
5230G **Ticarcillin with Clavulanic Acid,** powder for injection 3 g-100 mg (solvent required) **(Dental)**
(code 7043Q applies to above item with approved solvent)

ADVANCE NOTICES

Advance Notices — Deletion of Items

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 **February** 2007:

Item discontinued by the manufacturer —

8742D **Carvedilol,** pack containing 30 tablets 3.125 mg, 30 tablets 6.25 mg and 10 tablets 12.5 mg *(Dilatrend Titration Pack)*

The following items will be deleted from the **Highly Specialised Drugs Program** on 1 **March** 2007:

Items discontinued by the manufacturer —

6248W **Saquinavir,** soft gelatin capsule 200 mg *(Fortovase)*
6231Y **Nelfinavir Mesylate,** oral powder 50 mg (base) per g, 144 g *(Viracept)*

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **April** 2007:

Items discontinued by the manufacturer —

1508J **Hydroxocobalamin,** injection 1 mg in 1 mL *(Neo-Cytamen)*
2545Y **Oxandrolone,** tablet 2.5 mg *(Oxandrin)*

Advance Notices — Deletion of Brands

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 **February** 2007:

Brand discontinued by the manufacturer —

1356J *Nebcin, AS* — **Tobramycin Sulfate,** injection 80 mg (base) in 2 mL (with preservative)

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 **April** 2007:

Brands discontinued by the manufacturer —

1884E *Moxacin, CS* — **Amoxycillin,** capsule 250 mg
3301R *Moxacin, CS* — **Amoxycillin,** capsule 250 mg **(Dental)**
1886G *Moxacin, CS* — **Amoxycillin,** powder for syrup 125 mg per 5 mL, 100 mL
3302T *Moxacin, CS* — **Amoxycillin,** powder for syrup 125 mg per 5 mL, 100 mL **(Dental)**
1929M *Novantrone, SI* — **Mitozantrone Hydrochloride,** injection 20 mg (base) in 10 mL
1930N *Novantrone, SI* — **Mitozantrone Hydrochloride,** injection 25 mg (base) in 12.5 mL

RESTRICTIONS

Details of restriction text for new items and restriction alterations as noted above:

8757X **Ezetimibe,** tablet 10 mg *(Ezetrol)*

Authority required

- **Initial treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have:**
  (a) coronary heart disease; or
  (b) diabetes mellitus; or
  (c) peripheral vascular disease; or
  (d) heterozygous familial hypercholesterolaemia; or
  (e) symptomatic cerebrovascular disease.
  Inadequate control with a statin is defined as follows:
  (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy, a cholesterol level in excess of that threshold after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise; or
  (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level, a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise.
  The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application;
  Continuing treatment for co-administration with HMG CoA reductase inhibitors (statins) in patients with coronary heart disease or diabetes mellitus or peripheral vascular disease or heterozygous familial hypercholesterolaemia or symptomatic cerebrovascular disease whose cholesterol levels were inadequately controlled with a statin, where the patient has previously been issued with an authority prescription for this drug.

Authority required

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs):
(a) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated; or
(b) where treatment with an HMG CoA reductase inhibitor (statin) is unsuitable because the patient developed a clinically important product-related adverse event during treatment with a statin, and required discontinuation of all statin treatment.
A clinically important product-related adverse event is defined as follows:
(i) Severe myalgia (muscle symptoms without CK elevation) which is proven to be temporally associated with statin treatment; or
(ii) Myositis (clinically important CK elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Authority required

Homozygous sitosterolaemia;
Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin).

8881K **Ezetimibe with Simvastatin,** tablet 10 mg-40 mg *(Vytorin)*
8882L **Ezetimibe with Simvastatin,** tablet 10 mg-80 mg *(Vytorin)*

Authority required

- **Initial treatment, in conjunction with dietary therapy and exercise, in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) and who have:**
  (a) coronary heart disease; or
  (b) diabetes mellitus; or
  (c) peripheral vascular disease; or
  (d) heterozygous familial hypercholesterolaemia; or
  (e) cerebrovascular disease which has become symptomatic.
  Inadequate control with a statin is defined as follows:
  (1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy, a cholesterol level in excess of that threshold after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise; or
  (2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level, a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise.
  The cholesterol level after 3 months of treatment with a statin and the dose of the statin must be provided at the time of application. The cholesterol level results provided must be no more than 2 months old at the time of application;
  Continuing treatment in patients with coronary heart disease or diabetes mellitus or peripheral vascular disease or heterozygous familial hypercholesterolaemia or symptomatic cerebrovascular disease whose cholesterol levels were inadequately controlled with a statin, where the patient has previously been issued with an authority prescription for this item or the combination of ezetimibe and 40 mg or greater of a statin;
  Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

NOTES

Details of Notes for items mentioned above:

Oxaliplatin

The solution concentrate for I.V. infusion 50 mg and powder for I.V. infusion 50 mg (after reconstitution) are bioequivalent.

The solution concentrate for I.V. infusion 100 mg and powder for I.V. infusion 100 mg (after reconstitution) are bioequivalent.