Australian Government

Department of Health and Ageing

**SCHEDULE OF PHARMACEUTICAL BENEFITS**

# SUMMARY OF CHANGES

**EFFECTIVE 1 FEBRUARY 2009**

# PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 February 2009. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

## Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 February 2009 and are included, where applicable, in prices published in the Schedule—

| | | |
|---|---|---|
| Dispensing Fees: | Ready-prepared | $5.99 |
| | Dangerous drug fee | $2.71 |
| | Extemporaneously-prepared | $8.03 |
| | Allowable additional patient charge* | $3.79 |
| Additional Fees (for safety net prices): | Ready-prepared | $1.03 |
| | Extemporaneously-prepared | $1.39 |
| Patient Co-payments: | General | $32.90 |
| | Concessional | $5.30 |
| Safety Net Thresholds: | General | $1264.90 |
| | Concessional | $318.00 |
| Safety Net Card Issue Fee: | | $8.25 |

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

# SUMMARY OF CHANGES

## ADDITIONS

*Additions — Items*

(see under 'RESTRICTIONS' below for full details)

9366Y **Desvenlafaxine succinate**, Tablet 50 mg (base) (extended release) (*Pristiq*)

9367B **Desvenlafaxine succinate**, Tablet 100 mg (base) (extended release) (*Pristiq*)

9365X **Mirtazapine**, Tablet 15 mg (*Axit 15*)

9380Q **Sorafenib**, Tablet 200 mg (as tosylate) (*Nexavar*)

9378N **Triptorelin embonate**, Powder for I.M. injection (prolonged release) 3.75 mg (base) with solvent, syringe and needles (*Diphereline*)

9379P **Triptorelin embonate**, Powder for I.M. injection (prolonged release) 11.25 mg (base) with solvent, syringe and needles (*Diphereline*)

9363T **Voriconazole**, Tablet 50 mg (*Vfend*)

9364W **Voriconazole**, Tablet 200 mg (*Vfend*)

*Additions — Brands*

8511Y *Alendronate-GA, GM* — **Alendronate sodium**, Tablet equivalent to 70 mg alendronic acid

8255L *Vedilol 3.125, ZP* — **Carvedilol**, Tablet 3.125 mg

8256M *Vedilol 6.25, ZP* — **Carvedilol**, Tablet 6.25 mg

8257N *Vedilol 12.5, ZP* — **Carvedilol**, Tablet 12.5 mg

8258P *Vedilol 25, ZP* — **Carvedilol**, Tablet 25 mg

2456G *APO-Lisinopril, TX* — **Lisinopril**, Tablet 5 mg

2458J *APO-Lisinopril, TX* — **Lisinopril**, Tablet 20 mg

8887R *Movalis 7.5, SI* — **Meloxicam**, Capsule 7.5 mg

8888T *Movalis 15, SI* — **Meloxicam**, Capsule 15 mg

2430X *Metformin Ranbaxy, RA* — **Metformin hydrochloride**, Tablet 500 mg

1801T *Metformin Ranbaxy, RA* — **Metformin hydrochloride**, Tablet 850 mg

2011W *Simvastatin-Spirit 10 , ZP* — **Simvastatin**, Tablet 10 mg

9242K *Simvastatin-Spirit 10 , ZP* — **Simvastatin**, Tablet 10 mg **(Diff. Max. Rpts)**

2012X *Simvastatin-Spirit 20 , ZP* — **Simvastatin**, Tablet 20 mg

9243L *Simvastatin-Spirit 20 , ZP* — **Simvastatin**, Tablet 20 mg **(Diff. Max. Rpts)**

8173E *Simvastatin-Spirit 40 , ZP* — **Simvastatin**, Tablet 40 mg

9244M *Simvastatin-Spirit 40 , ZP* — **Simvastatin**, Tablet 40 mg **(Diff. Max. Rpts)**

8313M *Simvastatin-Spirit 80 , ZP* — **Simvastatin**, Tablet 80 mg

9245N *Simvastatin-Spirit 80 , ZP* — **Simvastatin**, Tablet 80 mg **(Diff. Max. Rpts)**

*Additions — Bioequivalence Indicators*

The bioequivalence indicator ([a]) has been added to the following brands:

8887R *Mobic , BY* — **Meloxicam**, Capsule 7.5 mg

8888T *Mobic , BY* — **Meloxicam**, Capsule 15 mg

## DELETIONS

*Deletions — Items*

8468Q **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine**, Infant formula, powder 350 g (*Ketonex-1*)

8469R **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine**, Powder 325 g (*Ketonex-2*)

*Deletions — Brands*

1081X *Anselol 50 mg, GM* — **Atenolol**, Tablet 50 mg

2792Y *Odrik, KN* — **Trandolapril**, Capsule 1 mg

2793B *Odrik, KN* — **Trandolapril**, Capsule 2 mg

## ALTERATIONS

*Alterations — Restrictions*

(see under 'RESTRICTIONS' below for full details)

Restrictions have been amended in respect of the following:

8358X **Clopidogrel hydrogen sulfate**, Tablet 75 mg (base) (*Iscover, Plavix*)

8481J **Risedronate sodium**, Tablet 5 mg (*Actonel*)

8621R **Risedronate sodium**, Tablet 35 mg (*Actonel Once-a-Week*)

8899J **Risedronate sodium and calcium carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) (*Actonel Combi*)

8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)

8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)

9059T **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-500 mg (*Avandamet*)

9060W **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-1 g (*Avandamet*)

9061X **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-500 mg (*Avandamet*)

9062Y **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-1 g (*Avandamet*)

*Alterations — Notes*

(see under 'RESTRICTIONS' below for full details)

Notes have been amended in respect of the following:

8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)

8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)

9059T **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-500 mg (*Avandamet*)

9060W **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-1 g (*Avandamet*)

9061X **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-500 mg (*Avandamet*)

9062Y **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-1 g (*Avandamet*)

*Alterations — Item Description*

*From:*

2265F **Influenza vaccine**, Injection (trivalent) 0.25 mL (containing A/Solomon Islands/3/2006, A/Brisbane/10/2007 and B/Florida/4/2006 like strains) (*Fluvax Junior, Vaxigrip Junior*)

*To:*

2265F **Influenza vaccine**, Injection (trivalent) 0.25 mL (containing A/Brisbane/59/2007, A/Brisbane/10/2007 and B/Florida/4/2006 like strains) (*Fluvax Junior, Vaxigrip Junior*)

*From:*

2852D **Influenza vaccine**, Injection (trivalent) 0.5 mL (containing A/Solomon Islands/3/2006, A/Brisbane/10/2007 and B/Florida/4/2006 like strains) (*Fluvax, Influvac, Vaxigrip*)

*To:*

2852D **Influenza vaccine**, Injection (trivalent) 0.5 mL (containing A/Brisbane/59/2007, A/Brisbane/10/2007 and B/Florida/4/2006 like strains) (*Fluvax, Influvac, Vaxigrip*)

*Alterations — Proprietary Name*

*From:*
8259Q **Protein hydrolysate formula with medium chain triglycerides**, Compound powder 450 g (*Pepti-Junior*)
*To:*
8259Q **Protein hydrolysate formula with medium chain triglycerides**, Compound powder 450 g (*Pepti-Junior Gold*)

*Alterations — Proprietary Name & Manufacturer's Code*

*From:*
2751T **Amlodipine**, Tablet 5 mg (as besylate) (*Amlotrust 5, MI*)
*To:*
2751T **Amlodipine**, Tablet 5 mg (as besylate) (*Pharmacor Amlodipine 5, CR*)
*From:*
2752W **Amlodipine**, Tablet 10 mg (as besylate) (*Amlotrust 10, MI*)
*To:*
2752W **Amlodipine**, Tablet 10 mg (as besylate) (*Pharmacor Amlodipine 10, CR*)

*Alterations — Manufacturer's Code*

All products previously listed under Organon (Australia) Pty Limited (OR) are now listed under Schering-Plough Pty Ltd (SH)

All products previously listed under British Pharmaceuticals (BP) are now listed under Schering-Plough Pty Ltd (SH)

| | | *From* | *To* |
|---|---|---|---|
| 8697R | **Adrenaline**, I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector (*EpiPen Jr.*) | CS | AL |
| 8698T | **Adrenaline**, I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector (*EpiPen*) | CS | AL |

# SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

## ALTERATIONS

*Alterations — Manufacturer's Code*

All products previously listed under Organon (Australia) Pty Limited (OR) are now listed under Schering-Plough Pty Ltd (SH)

*Alterations — Restrictions*

(see under 'RESTRICTIONS' below for full details)

6126K **Filgrastim**, Injection 300 micrograms in 1 mL (*Neupogen*)

6291D **Filgrastim**, Injection 300 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)
6127L **Filgrastim**, Injection 480 micrograms in 1.6 mL (*Neupogen*)

6292E **Filgrastim**, Injection 480 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)

6363X **Pegfilgrastim**, Injection 6 mg in 0.6 mL single use pre-filled syringe (*Neulasta*)

# SECTION 100 — IVF/GIFT PROGRAM

## ALTERATIONS

*Alterations — Manufacturer's Code*

All products previously listed under Organon (Australia) Pty Limited (OR) are now listed under Schering-Plough Pty Ltd (SH)

## ADVANCE NOTICES

*Advance Notice — Deletion of Brands*

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2009:
Brand discontinued by the manufacturer —

8839F *Attenta, AF* — **Methylphenidate hydrochloride**, Tablet 10 mg

# RESTRICTIONS

The text of restrictions mentioned above:

8358X **Clopidogrel hydrogen sulfate**, Tablet 75 mg (base) (*Iscover*, *Plavix*)

**Authority required (STREAMLINED)**

**1719**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients with a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin

**Authority required (STREAMLINED)**

**1720**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

**Authority required (STREAMLINED)**

**1721**

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Authority required (STREAMLINED)**

**1722**

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin

**Authority required (STREAMLINED)**

**1723**

Prevention of recurrence of myocardial infarction or unstable angina in patients where low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding

**Authority required (STREAMLINED)**

**1724**

Prevention of recurrence of myocardial infarction or unstable angina in patients where there is a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or NSAIDs

**Authority required (STREAMLINED)**

**3069**

Treatment of acute coronary syndromes (myocardial infarction or unstable angina) in combination with aspirin to prevent early and long-term atherothrombotic events

**NOTE:**

Not for prophylaxis of DVT or peripheral arterial disease

9367B **Desvenlafaxine succinate**, Tablet 100 mg (base) (extended release) (*Pristiq*)
9366Y **Desvenlafaxine succinate**, Tablet 50 mg (base) (extended release) (*Pristiq*)
9365X **Mirtazapine**, Tablet 15 mg (*Axit 15*)

**Restricted benefit**

Major depressive disorders

6291D **Filgrastim**, Injection 300 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)
6126K **Filgrastim**, Injection 300 micrograms in 1 mL (*Neupogen*)
6292E **Filgrastim**, Injection 480 micrograms in 0.5 mL single use pre-filled syringe (*Neupogen*)

6127L **Filgrastim**, Injection 480 micrograms in 1.6 mL (*Neupogen*)

**Private hospital authority required**

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Private hospital authority required**

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

**Private hospital authority required**

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

**Private hospital authority required**

A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation

**Private hospital authority required**

A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation

**Private hospital authority required**

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Private hospital authority required**

A patient receiving first-line chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Private hospital authority required**

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Private hospital authority required**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Private hospital authority required**

A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

**Private hospital authority required**

A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Private hospital authority required**

A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

6363X **Pegfilgrastim**, Injection 6 mg in 0.6 mL single use pre-filled syringe (*Neulasta*)

**Private hospital authority required**

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

**Private hospital authority required**

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Private hospital authority required**

A patient receiving first-line chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Private hospital authority required**

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Private hospital authority required**

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

**Private hospital authority required**

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

8621R **Risedronate sodium**, Tablet 35 mg (*Actonel Once-a-Week*)

8481J **Risedronate sodium**, Tablet 5 mg (*Actonel*)

8899J **Risedronate sodium and calcium carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) (*Actonel Combi*)

**Authority required (STREAMLINED)**

**3070**

Treatment as the sole PBS-subsidised anti-resorptive agent for corticosteroid-induced osteoporosis in a patient currently on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy with a Bone Mineral Density (BMD) T-score of -1.5 or less.The

duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated

**Authority required (STREAMLINED)**

**2645**

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated

**Authority required (STREAMLINED)**

**2646**

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body

**NOTE:**

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride, strontium ranelate and zoledronic acid

8689H **Rosiglitazone maleate**, Tablet 4 mg (base) (*Avandia*)

8690J **Rosiglitazone maleate**, Tablet 8 mg (base) (*Avandia*)

**Authority required (STREAMLINED)**

**2635**

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with either metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with either metformin or a sulfonylurea and where a combination of metformin and a sulfonylurea is contraindicated or not tolerated.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated

**NOTE:**

Rosiglitazone maleate is not PBS-subsidised as monotherapy.

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

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records.

9060W **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-1 g (*Avandamet*)
9059T **Rosiglitazone maleate with metformin hydrochloride**, Tablet 2 mg (base)-500 mg (*Avandamet*)
9062Y **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-1 g (*Avandamet*)

9061X **Rosiglitazone maleate with metformin hydrochloride**, Tablet 4 mg (base)-500 mg (*Avandamet*)

**NOTE:**

Rosiglitazone with metformin fixed dose combination tablet is not PBS-subsidised when used in combination with insulin

**Authority required (STREAMLINED)**

**2633**

Type 2 diabetes in a patient whose HbA1c is greater than 7% prior to initiation of a thiazolidinedione (glitazone) despite treatment with metformin and where a sulfonylurea is contraindicated or not tolerated.

The date and level of the HbA1c must be documented in the patient's medical records at the time glitazone treatment is initiated. The HbA1c must be no more than 4 months old at the time glitazone treatment is initiated

**NOTE:**

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

(a) clinical conditions with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) red cell transfusion within the previous 3 months.

A patient in these circumstances will be eligible for treatment where blood glucose monitoring over a 2 week period shows blood glucose levels greater than 10 mmol per L in more than 20% of tests. The results of this blood glucose monitoring, which must be no more than 4 months old at the time of initiation of glitazone therapy, must be documented in the patient's medical records

9380Q **Sorafenib**, Tablet 200 mg (as tosylate) (*Nexavar*)

**Authority required**

Initial treatment, as the sole PBS-subsidised agent, of advanced (BCLC Stage C) hepatocellular carcinoma in a patient with a WHO performance status of 2 or less and Child Pugh class A

**Authority required**

Continuing treatment, as the sole PBS-subsidised agent, of advanced hepatocellular carcinoma in a patient who has previously been treated with PBS-subsidised sorafenib and who does not have progressive disease

**NOTE:**

Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization

Sorafenib is not PBS-subsidised for maintenance therapy after disease progression

No applications for increased maximum quantities and/or repeats will be authorised

9379P **Triptorelin embonate**, Powder for I.M. injection (prolonged release) 11.25 mg (base) with solvent, syringe and needles (*Diphereline*)

9378N **Triptorelin embonate**, Powder for I.M. injection (prolonged release) 3.75 mg (base) with solvent, syringe and needles (*Diphereline*)

**Authority required**

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

9364W **Voriconazole**, Tablet 200 mg (*Vfend*)

9363T **Voriconazole**, Tablet 50 mg (*Vfend*)

**Authority required**

For the treatment and maintenance therapy of definite or probable invasive aspergillosis in immunocompromised patients

**Authority required**

For the treatment and maintenance therapy of serious fungal infections caused by Scedosporium species or Fusarium species

**Authority required**

For the treatment and maintenance therapy of serious Candida infections where

treatment with amphotericin has failed

**Authority required**

For the treatment and maintenance therapy of serious Candida infections where

treatment with amphotericin is not tolerated and the causative species is not susceptible to fluconazole

**Authority required**

For the treatment and maintenance therapy of serious Candida infections where

treatment with fluconazole has failed

**Authority required**

For the treatment and maintenance therapy of serious Candida infections where

treatment with fluconazole is not tolerated

**Authority required**

For the treatment and maintenance therapy of other serious invasive mycosis where

treatment with amphotericin has failed

**Authority required**

For the treatment and maintenance therapy of other serious invasive mycosis where

treatment with amphotericin is not tolerated

# REPATRIATION PHARMACEUTICAL BENEFITS

***This Schedule is effective from 1 February 2009 and all previous issues are cancelled. New Schedules take effect on the first day of each month.***

## SUMMARY OF CHANGES

### ADDITIONS

*Additions — Items*

4082W **Calcium**, Tablet 600 mg (as carbonate) (*CAL-600*)
**Restricted**
Hypocalcaemia;
Osteoporosis;
Proven calcium malabsorption

4142B **Calcium**, Tablet 600 mg (as carbonate) (*CAL-600*) **(Diff. Max. Qty)**
**Restricted**
Hyperphosphataemia in chronic renal failure

4134N **Imiquimod**, Cream 50 mg per g (5%), 250 mg single use sachets, 12 (*Aldara*)
**Authority required**
Treatment of solar keratosis on the face and scalp in patients where other standard treatments are inappropriate and topical drug therapy is required as field treatment for clinically visible and subclinical lesions

*Additions — Brands*

4175R *Zilarex, SZ* — **Cetirizine hydrochloride**, Tablet 10 mg
4237B *Fexal, SZ* — **Fexofenadine hydrochloride**, Tablet 60 mg
4238C *Fexal, SZ* — **Fexofenadine hydrochloride**, Tablet 120 mg
4233T *Finasta, SZ* — **Finasteride**, Tablet 5 mg
4321K *Mag-Sup, PP* — **Magnesium aspartate**, Tablet 500 mg

*Addition — Note*

4648P **Dressing with silver**, Tulle dressings 10 cm x 10 cm, 3 (*Atrauman Ag 499572*)
**NOTE:**
Hartmann products are not available through pharmacy wholesalers. To order please contact the Hartmann Alliance (refer to 'Ordering Hartmann Products' at the foot of the 'Wound Assessment and Dressing Identification' chart at the beginning of this section).

*Addition — Bioequivalence Indicator*

The bioequivalence indicator ([a]) has been added to the following brand:

4233T **Finasteride**, Tablet 5 mg (*Proscar*)

## DELETIONS

*Deletions — Brands*

4014G *Canesten, BN* — **Clotrimazole**, Pessaries 100 mg, 6

4015H *Canesten 1, BN* — **Clotrimazole**, Pessary 500 mg

4016J *Canesten, BN* — **Clotrimazole**, Vaginal cream 50 mg per 5 g (1%), 35 g

4017K *Canesten 3, BN* — **Clotrimazole**, Vaginal cream 100 mg per 5 g (2%), 20 g

## ALTERATIONS

*Alterations — Item Description*

*From:*

4560B **Salicylic acid with benzalkonium chloride, alcohol, coal tar and polyoxyethylene ethers**, Scalp cleanser 20 mg-2 mg-130 mg-50 mg-216 mg per mL (2%-0.2%-13%-5%-21.6%), 250 mL (*Ionil-T*)

*To:*

4560B **Salicylic acid with coal tar solution**, Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL (*Ionil-T*)

*Alterations — Manufacturer's Code*

| | | *From* | *To* |
|---|---|---|---|
| 4313B | **Loratadine**, Tablet 10 mg (*Lorano*) | HX | SZ |
| 4365R | **Oestradiol**, Implant 50 mg (*SH*) | OR | SH |
| 4366T | **Oestradiol**, Implant 100 mg (*SH*) | OR | SH |