Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

SUMMARY OF CHANGES

EFFECTIVE 1 FEBRUARY 2007 – 28 FEBRUARY 2007

PHARMACEUTICAL BENEFITS

This Schedule will take effect on 1 February 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 February 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

2480M **Ciprofloxacin,** ear drops 3 mg per mL (0.3%), 5 mL *(Ciloxan)*

Additions — Brands

8255L *GenRx Carvedilol, GX* — **Carvedilol,** tablet 3.125 mg
8256M *GenRx Carvedilol, GX* — **Carvedilol,** tablet 6.25 mg
8257N *GenRx Carvedilol, GX* — **Carvedilol,** tablet 12.5 mg
8258P *GenRx Carvedilol, GX* — **Carvedilol,** tablet 25 mg
8450R *Glimepiride Sandoz, SZ* — **Glimepiride,** tablet 1 mg
8451T *Glimepiride Sandoz, SZ* — **Glimepiride,** tablet 2 mg
8533D *Glimepiride Sandoz, SZ* — **Glimepiride,** tablet 3 mg
8452W *Glimepiride Sandoz, SZ* — **Glimepiride,** tablet 4 mg
8331L *Omeprazole Winthrop, SL* — **Omeprazole,** tablet 20 mg
8333N *Omeprazole Winthrop, SL* — **Omeprazole,** tablet 20 mg **(Diff. Max. Rpts)**
1944H *Ramipril Sandoz, QM; Ramipril Winthrop, WA* — **Ramipril,** tablet 1.25 mg
1945J *Ramipril Sandoz, QM; Ramipril Winthrop, WA* — **Ramipril,** tablet 2.5 mg
1946K *Ramipril Sandoz, QM; Ramipril Winthrop, WA* — **Ramipril,** tablet 5 mg

8470T *Ramipril Sandoz, QM; Ramipril Winthrop, WA* — **Ramipril,** capsule 10 mg
1978D *Ulcaid (RA)* — **Ranitidine Hydrochloride,** tablet 150 mg (base)
1977C *Ulcaid (RA)* — **Ranitidine Hydrochloride,** tablet 300 mg (base)
1760P *Roxide (HX)* — **Roxithromycin,** tablet 150 mg
8016X *Roxide (HX)* — **Roxithromycin,** tablet 300 mg

DELETIONS

Deletions — Items

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

Deletions — Brands

8511Y *Chem mart Alendronate, CH; GenRx Alendronate, GX; Terry White Chemists Alendronate, TW* — **Alendronate Sodium,** tablet equivalent to 70 mg alendronic acid
1356J *Nebcin, AS* — **Tobramycin Sulfate,** injection 80 mg (base) in 2 mL (with preservative)

Deletions — PBS Therapeutic Group Premium Exemption Codes

8945T **Ramipril,** tablet 1.25 mg *(Ramace 1.25 mg, Tritace 1.25 mg)*
8946W **Ramipril,** tablet 2.5 mg *(Ramace 2.5 mg, Tritace 2.5 mg)*
8947X **Ramipril,** tablet 5 mg *(Ramace 5 mg, Tritace 5 mg)*
8937J **Ramipril,** capsule 10 mg *(Ramace 10 mg, Tritace 10 mg)*

ALTERATIONS

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

8664B **Riluzole,** tablet 50 mg *(Rilutek)*
8816B **Modafinil,** tablet 100 mg *(Modavigil)*

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

Notes have been amended in respect of the following:

Disodium Pamidronate
Epirubicin Hydrochloride

Alterations — Item Description

From:
2852D **Influenza Vaccine,** injection (trivalent) 0.5 mL (containing A/New Caledonia/20/99, A/California/7/2004 and B/Malaysia/2506/2004 like strains)
To:
2852D **Influenza Vaccine,** injection (trivalent) 0.5 mL (containing A/New Caledonia/20/99, A/Wisconsin/67/2005 and B/Malaysia/2506/2004 like strains)

Alterations — Number of Repeats

		From	*To*
8506Q	**Exemestane,** tablet 25 mg *(Aromasin)*	2	5
8245Y	**Letrozole,** tablet 2.5 mg *(Femara 2.5 mg)*	2	5

Alterations — Manufacturer's Code

		From	*To*
1081X	**Atenolol,** tablet 50 mg *(Atehexal)*	HX	SZ
8220P	**Citalopram Hydrobromide,** tablet 20 mg (base) *(Talohexal)*	HX	SZ
8703C	**Citalopram Hydrobromide,** tablet 40 mg (base) *(Talohexal)*	HX	SZ
2711Q	**Doxycycline,** tablet 50 mg *(Doxyhexal)*	HX	SZ
2709N	**Doxycycline,** tablet 100 mg *(Doxyhexal)*	HX	SZ
2702F	**Doxycycline,** tablet 100 mg *(Doxyhexal)* **(Diff. Max. Qty)**	HX	SZ
2714W	**Doxycycline,** tablet 100 mg *(Doxyhexal)* **(Diff. Max. Qty)**	HX	SZ
3321T	**Doxycycline,** tablet 100 mg *(Doxyhexal)* **(Dental)**	HX	SZ
2242B	**Paroxetine,** tablet 20 mg (base) *(Oxetine)*	HX	SZ
2236Q	**Sertraline Hydrochloride,** tablet 50 mg (base) *(Concorz)*	HX	SZ
2237R	**Sertraline Hydrochloride,** tablet 100 mg (base) *(Concorz)*	HX	SZ
2804N	**Terbinafine Hydrochloride,** tablet 250 mg (base) *(Terbihexal)*	HX	SZ

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

DELETIONS

Deletions — Items

9601H **Pegfilgrastim,** injection 6 mg in 0.6 mL single-use pre-filled injection pen *(Neulasta SureClick)*

ALTERATIONS

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

Notes have been amended in respect of the following:

Disodium Pamidronate

SECTION 100 — SPECIAL AUTHORITY PROGRAM

ALTERATIONS

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

6444E **Imatinib Mesylate,** tablet 100 mg (base) *(Glivec)*
6445F **Imatinib Mesylate,** tablet 400 mg (base) *(Glivec)*

ADVANCE NOTICES

Advance Notices — Deletion of Items

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 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,** injection 20 mg (base) in 10 mL
1930N *Novantrone, SI* — **Mitozantrone,** injection 25 mg (base) in 12.5 mL

REPATRIATION PHARMACEUTICAL BENEFITS

DELETIONS

Deletions — RPBS Therapeutic Group Premium Exemption Codes

4985J **Amlodipine Besylate,** tablet 5 mg (base) *(Norvasc)*
4986K **Amlodipine Besylate,** tablet 10 mg (base) *(Norvasc)*
4960C **Lercanidipine Hydrochloride,** tablet 10 mg *(Zanidip)*
4959B **Lercanidipine Hydrochloride,** tablet 20 mg *(Zanidip)*
4961D **Nifedipine,** tablet 20 mg (controlled release)*(Adalat Oros 20 mg)*
4951N **Ramipril,** tablet 1.25 mg *(Ramace 1.25 mg, Tritace 1.25 mg)*
4952P **Ramipril,** tablet 2.5 mg *(Ramace 2.5 mg, Tritace 2.5 mg)*
4953Q **Ramipril,** tablet 5 mg *(Ramace 5 mg, Tritace 5 mg)*
4962E **Ramipril,** capsule 10 mg *(Ramace 10 mg, Tritace 10 mg)*
4954R **Ramipril,** pack containing 7 tablets 2.5 mg, 21 tablets 5 mg and 10 capsules 10 mg *(Tritace Titration Pack)*
4978B **Ranitidine Hydrochloride,** effervescent tablet 150 mg (base) *(Zantac)*
4980D **Ranitidine Hydrochloride,** syrup 150 mg (base) per 10 mL, 300 mL *(Zantac Syrup)*

ALTERATIONS

Alterations — Manufacturer's Code

		From	*To*
4462W	**Sorbitol with Sodium Citrate and Sodium Lauryl Sulfoacetate,** enemas 3.125 g-450 mg-45 mg in 5 mL, 4 *(Microlax)*	PH	PC
4576W	**Nicotine,** transdermal patches releasing approximately 5 mg per 16 hours, 7 *(Nicorette Patch)*	PH	PC
4577X	**Nicotine,** transdermal patches releasing approximately 10 mg per 16 hours, 7 *(Nicorette Patch)*	PH	PC
4578Y	**Nicotine,** transdermal patches releasing approximately 15 mg per 16 hours, 7 *(Nicorette Patch)*	PH	PC

RESTRICTIONS

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

2480M **Ciprofloxacin,** ear drops 3 mg per mL (0.3%), 5 mL *(Ciloxan)*

Authority required
Treatment of chronic suppurative otitis media in an Aboriginal or a Torres Strait Islander person aged 1 year and older.

8664B **Riluzole,** tablet 50 mg *(Rilutek)*

Authority required
Initial treatment of amyotrophic lateral sclerosis, as diagnosed by a neurologist, in patients with disease duration of 2 years or less and who have at least 60 percent of predicted forced vital capacity within 2 months prior to commencing riluzole therapy and who:
(1) are ambulatory, and
(a) have not undergone tracheostomy, and
(b) have not experienced respiratory failure;
OR
(2) are not ambulatory, and
(a) have not undergone tracheostomy, and
(b) have not experienced respiratory failure, and
(c) are either able to use upper limbs or able to swallow.
The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

Authority required
Continuing treatment of amyotrophic lateral sclerosis in patients who have previously been issued with an authority prescription for this drug and who:
(1) are ambulatory, and
(a) have not undergone tracheostomy, and
(b) have not experienced respiratory failure;
OR
(2) are not ambulatory, and
(a) have not undergone tracheostomy, and
(b) have not experienced respiratory failure, and
(c) are either able to use upper limbs or able to swallow.

8816B **Modafinil,** tablet 100 mg *(Modavigil)*

Authority required

Initial treatment, by a qualified sleep medicine practitioner or neurologist, of patients with narcolepsy where:
(i) therapy with dexamphetamine sulfate poses an unacceptable medical risk; or
(ii) intolerance to dexamphetamine sulfate of a severity necessitating permanent treatment withdrawal develops.

The presence of any 1 of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:
(a) a psychiatric disorder;
(b) a cardiac disorder;
(c) a history of substance abuse;
(d) glaucoma;
(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

Patients must meet the following definition of narcolepsy:
Excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months and:
(i) a definite history of cataplexy and a Multiple Sleep Latency Test (MSLT) with a mean sleep latency less than or equal to 8 minutes; or
(ii) a MSLT with a mean sleep latency less than or equal to 8 minutes and 2 or more sleep onset rapid eye movement (REM) periods; or
(iii) an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours.

The authority application must be made in writing and must include the following:
(a) a completed authority prescription form; and
(b) a completed Modafinil (Modavigil) PBS Authority Application for Use in the Treatment of Narcolepsy - Supporting Information Form [www.medicareaustralia.gov.au]; and
(c) details of the contraindication or intolerance to dexamphetamine sulfate; and
(d) either:
(i) the result and date of the polysomnography test and MSLT conducted by, or under the supervision of, a qualified sleep medicine practitioner; or
(ii) the result and date of the EEG, conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Continuing treatment of narcolepsy, where the patient has previously been issued with an authority prescription for this drug.

SECTION 100 — SPECIAL AUTHORITY PROGRAM

6444E **Imatinib Mesylate,** tablet 100 mg (base) *(Glivec)*
6445F **Imatinib Mesylate,** tablet 400 mg (base) *(Glivec)*

Section 100 authority required

Initial treatment of patients in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy from the date the first application for initial treatment was approved.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the bcr-abl transcript in either peripheral blood or bone marrow; and
(4) a copy of a signed patient acknowledgement form indicating that the patient understands and acknowledges that PBS-subsidised treatment with imatinib mesylate for the chronic phase of chronic myeloid leukaemia will cease if subsequent testing demonstrates that:
(i) the patient has failed to achieve a major cytogenetic response within the initial 18 months of treatment [see Note defining major cytogenetic response]; or
(ii) the patient has failed to sustain a major cytogenetic response for 12 months from the date of the last pathology report that indicated that a major cytogenetic response had been achieved [see Note defining major cytogenetic response].

NOTE:
Imatinib mesylate in the chronic phase of chronic myeloid leukaemia will only be subsidised for patients who are not receiving concomitant PBS-subsidised interferon alfa therapy.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily and maintained on a minimum dose of imatinib mesylate of 400 mg (base) daily. Prescribing of lower doses should be carefully considered. Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter, irrespective of the daily imatinib mesylate dose received.

Section 100 authority required

Continuing treatment of patients who have received initial treatment with imatinib mesylate as a pharmaceutical benefit for the chronic phase of chronic myeloid leukaemia and who have demonstrated either a major cytogenetic response or less than 1% bcr-abl level in the blood in the preceding 12 months.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) demonstration of continued response to treatment as evidenced by either:
(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or
(b) a peripheral blood level of bcr-abl of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided.

NOTE:

Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood bcr-abl level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of bcr-abl transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with bcr-abl specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:
(i) between 10 and 12 months of the commencement of treatment with imatinib mesylate, at which time patients in whom a major cytogenetic response or peripheral blood bcr-abl level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) within 18 months of the commencement of treatment with imatinib mesylate, in patients who have failed to demonstrate a major cytogenetic response or peripheral blood bcr-abl level of less than 1% at between 10 and 12 months (patients in whom a major cytogenetic response or peripheral blood bcr-abl level of less than 1% is demonstrable by 18 months may also receive authorisation for a further 12 months of treatment); and
(iii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood bcr-abl level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of bcr-abl transcript in the peripheral blood using the international scale, must be submitted as described in (i) to (iii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with bcr-abl specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the criteria for continuing treatment.

NOTES

Details of Notes for items mentioned above:

Disodium Pamidronate

The concentrated injection 15 mg and powder for I.V. infusion 15 mg (after reconstitution) are bioequivalent.

The concentrated injection 30 mg and powder for I.V. infusion 30 mg (after reconstitution) are bioequivalent.

Epirubicin Hydrochloride

The solution for injection 50 mg and powder for injection 50 mg (after reconstitution) are bioequivalent.

SECTION 100 — HIGHLY SPECIALISED DRUGS PROGRAM

Disodium Pamidronate

The concentrated injection 15 mg and powder for I.V. infusion 15 mg (after reconstitution) are bioequivalent.

The concentrated injection 30 mg and powder for I.V. infusion 30 mg (after reconstitution) are bioequivalent.

The concentrated injection 90 mg and powder for I.V. infusion 90 mg (after reconstitution) are bioequivalent.