Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 APRIL 2009

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 April 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 April 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' and 'NOTES' below for full details)

9396M **Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 125 mL, 36 (*PKU Anamix Junior LQ*)

9397N **Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 62.5 mL, 60 (*Lophlex LQ 10*)

9395L **Amino acid formula with vitamins and minerals without phenylalanine and tyrosine**, Sachets 29 g, 30 (*TYR Anamix Junior*)

9398P **Desmopressin acetate**, Wafer 120 micrograms (base) (*Minirin Melt*)

9401T **Gemcitabine hydrochloride**, Solution concentrate for I.V. infusion 200 mg (base) in 20 mL (*Gemcitabine Ebewe*)

9402W **Gemcitabine hydrochloride**, Solution concentrate for I.V. infusion 1000 mg (base) in 100 mL (*Gemcitabine Ebewe*)

9399Q **Oxycodone hydrochloride**, Tablet 15 mg (controlled release) (*OxyContin*)

5015Y **Oxycodone hydrochloride**, Tablet 15 mg (controlled release) (*OxyContin*) **(Dental)**

9400R **Oxycodone hydrochloride**, Tablet 30 mg (controlled release) (*OxyContin*)

5016B **Oxycodone hydrochloride**, Tablet 30 mg (controlled release) (*OxyContin*) **(Dental)**

9393J **Pramipexole hydrochloride**, Tablet 125 micrograms (*Sifrol*) **(Diff. Max. Rpts)**

9394K **Pramipexole hydrochloride**, Tablet 250 micrograms (*Sifrol*) **(Diff. Max. Rpts)**

9388D **Zonisamide**, Capsule 25 mg (*Zonegran*)

9389E **Zonisamide**, Capsule 50 mg (*Zonegran*)

9390F **Zonisamide**, Capsule 100 mg (*Zonegran*)

Additions – Brands

1370D *Enalapril generichealth, GQ* — **Enalapril maleate**, Tablet 5 mg

1368B *Enalapril generichealth, GQ* — **Enalapril maleate**, Tablet 10 mg

1369C *Enalapril generichealth, GQ* — **Enalapril maleate**, Tablet 20 mg

8512B *APO-Fluvoxamine, TX* — **Fluvoxamine maleate**, Tablet 50 mg

8174F *APO-Fluvoxamine, TX* — **Fluvoxamine maleate**, Tablet 100 mg

8535F *Glyade MR, AF* — **Gliclazide**, Tablet 30 mg (modified release)

2457H *APO-Lisinopril, TX* — **Lisinopril**, Tablet 10 mg

8884N *Diaformin XR, AF* — **Metformin hydrochloride**, Tablet 500 mg (extended release)

8607B *Metformin-GA, GN* — **Metformin hydrochloride**, Tablet 1 g

8331L *APO-Omeprazole, TX* — **Omeprazole**, Tablet 20 mg

8333N *APO-Omeprazole, TX* — **Omeprazole**, Tablet 20 mg **(Diff. Max. Rpts)**

Additions – Bioequivalence Indicator

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

8049P *Gemzar, LY* — **Gemcitabine hydrochloride**, Powder for I.V. infusion 200 mg (base)

8050Q *Gemzar, LY* — **Gemcitabine hydrochloride**, Powder for I.V. infusion 1 g (base)

DELETIONS

Deletions – Item

2576N **Aluminium hydroxide with magnesium hydroxide**, Tablet 200 mg-200 mg (*Mylanta P*)

Deletions – Item (PBS Authority Required Special Patient Contribution Exemption Codes)

9700M **Escitalopram oxalate**, Oral solution 10 mg (base) per mL, 28 mL (*Lexapro*) **(Special Pharmaceutical Benefit)**

Deletions – Brands

8318T *APO-Clarithromycin, TX* — **Clarithromycin**, Tablet 250 mg

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

Deletions – Bioequivalence Indicator

The bioequivalence indicator (a) has been removed from the following brand:

8839F *Ritalin 10, NV* — **Methylphenidate hydrochloride**, Tablet 10 mg

ALTERATIONS

Alterations – Item Description

From:
1411G **Amino acid formula without phenylalanine, and vitamins with minerals**, Pack containing 60 sachets of phenylalanine-free amino acid formula powder 17 g, and 60 tablets containing vitamins and minerals (*add-ins*)
To:
1411G **Amino acid formula with vitamins and minerals without phenylalanine**, Sachets 18.2 g, 60 (*add-ins*)
From:
8384G **Carbomer 980**, Ocular lubricating gel 2 mg per g (0.2%), 10 g (*GelTears, PAA, Viscotears Liquid Gel*)
To:
8384G **Carbomer**, Eye gel 2 mg per g (0.2%), 10 g (*GelTears, PAA, Viscotears*)
From:
9210R **Carbomer 980**, Ocular lubricating gel 2 mg per g (0.2%), 10 g (*GelTears, PAA, Viscotears Liquid Gel*)
To:
9210R **Carbomer**, Eye gel 2 mg per g (0.2%), 10 g (*GelTears, PAA, Viscotears*) **(Diff. Max. Rpts)**
From:
8578L **Carbomer 980**, Eye drops 2 mg per g (0.2%), single dose units 0.6 mL, 30 (*Viscotears*)
To:
8578L **Carbomer**, Eye gel 2 mg per g (0.2%), single dose units 0.6 mL, 30 (*Viscotears*)
From:
5503P **Carbomer 980**, Ocular lubricating gel 2 mg per g (0.2%), 10 g (*GelTears, PAA, Viscotears Liquid Gel*) **(Optometrical)**
To:
5503P **Carbomer**, Eye gel 2 mg per g (0.2%), 10 g (*GelTears, PAA, Viscotears*) **(Optometrical)**

From:

5504Q **Carbomer 980**, Eye drops 2 mg per g (0.2%), single dose units 0.6 mL, 30 (*Viscotears*) **(Optometrical)**

To:

5504Q **Carbomer**, Eye gel 2 mg per g (0.2%), single dose units 0.6 mL, 30 (*Viscotears*) **(Optometrical)**

From:

8101J **Interferon beta-1b**, Injection set comprising 1 vial powder for injection 8,000,000 i.u. (250 micrograms) and solvent (*Betaferon*)

To:

8101J **Interferon beta-1b**, Injection set including 1 vial powder for injection 8,000,000 i.u. (250 micrograms) and solvent (*Betaferon*)

From:

1382R **Ranibizumab**, Solution for intravitreal injection 3 mg in 0.3 mL (*Lucentis*)

To:

1382R **Ranibizumab**, Solution for intravitreal injection 2.3 mg in 0.23 mL (*Lucentis*)

Alterations – Maximum Quantity

		From	*To*
8558K	**Enoxaparin sodium**, Injection 20 mg (2,000 i.u. anti-Xa) in 0.2 mL pre-filled syringe (*Clexane*)	10	20
8510X	**Enoxaparin sodium**, Injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe (*Clexane*)	10	20
9195Y	**Enoxaparin sodium**, Solution for injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL (*Clexane*)	10	20

Alterations – Number of Repeats

		From	*To*
8558K	**Enoxaparin sodium**, Injection 20 mg (2,000 i.u. anti-Xa) in 0.2 mL pre-filled syringe (*Clexane*)	1	0
8510X	**Enoxaparin sodium**, Injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL pre-filled syringe (*Clexane*)	1	0
9195Y	**Enoxaparin sodium**, Solution for injection 40 mg (4,000 i.u. anti-Xa) in 0.4 mL (*Clexane*)	1	0

Alterations – Notes

(see under 'NOTES' below for full details)

8663Y **Desmopressin acetate**, Tablet 200 micrograms (*Minirin*)

8712M **Desmopressin acetate**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL

Alterations – Restrictions

(see under 'RESTRICTIONS' below for full details)

9033K **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*) [Initial 1 restriction for patients with psoriatic arthritis]

9101B **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) [Initial 1 restriction for patients with psoriatic arthritis]

8849R **Escitalopram oxalate**, Oral solution 10 mg (base) per mL, 28 mL (*Lexapro*)
9035M **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) [Initial 1 restriction for patients with psoriatic arthritis]
9083C **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) [Initial 1 restriction for patients with psoriatic arthritis]
9087G **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [Initial 1 restriction for patients with psoriatic arthritis]
9147K **Risedronate sodium and calcium carbonate with colecalciferol**, Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms (Actonel Combi D) [the addition of Authority required (STREAMLINED) restriction 3070 for the treatment of corticosteroid-induced osteoporosis]
9180E **Sitagliptin**, Tablet 25 mg (as phosphate monohydrate) (*Januvia*)
9181F **Sitagliptin**, Tablet 50 mg (as phosphate monohydrate) (*Januvia*)
9182G **Sitagliptin**, Tablet 100 mg (as phosphate monohydrate) (*Januvia*)
9070J **Ziprasidone hydrochloride**, Capsule 20 mg (base) (*Zeldox*)
9071K **Ziprasidone hydrochloride**, Capsule 40 mg (base) (*Zeldox*)
9072L **Ziprasidone hydrochloride**, Capsule 60 mg (base) (*Zeldox*)
9073M **Ziprasidone hydrochloride**, Capsule 80 mg (base) (*Zeldox*)
9288W **Zoledronic acid**, Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL (*Aclasta*)

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

ALTERATIONS

Alterations – Manufacturer's Code

		From	*To*
6469L	**Thalidomide**, Capsule 50 mg (*Thalidomide Pharmion*)	PI	CJ

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*)
6496X **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) [Initial 1 restriction for patients with psoriatic arthritis]
6363X **Pegfilgrastim**, Injection 6 mg in 0.6 mL single use pre-filled syringe (*Neulasta*)

SECTION 100 – BOTULINUM TOXIN PROGRAM

ALTERATIONS

Alterations – Restrictions

(see under 'RESTRICTIONS' below for full details)

6103F **Botulinum toxin type A purified neurotoxin complex**, Lyophilised powder for I.M. injection 100 units (*Botox*)

6293F **Clostridium botulinum type A toxin—haemagglutinin complex**, Lyophilised powder for I.M. injection 500 units (*Dysport*)

ADVANCE NOTICES

Advance Notice — Deletion of Item

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 June 2009:

Deletion requested by the manufacturer —

8818D **Metoprolol succinate**, Pack containing 15 tablets 23.75 mg (controlled release), 15 tablets 47.5 mg (controlled release) and 15 tablets 95 mg (controlled release) (*Toprol-XL Titration Pack*)

Advance Notice – Deletion of Brand

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 June 2009:

Deletions requested by the manufacturer —

2592K *Chem mart Isotretinoin, CH; Terry White Chemists Isotretinoin, TW* — **Isotretinoin**, Capsule 20 mg

RESTRICTIONS

The text of restrictions mentioned above:

9101B **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

9033K **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

NOTE:

Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe adalimumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 1

Initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and

(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and

(3) have failed to achieve an adequate response to:

(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and

(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or

(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.Applications for treatment with adalimumab where the dosing frequency exceeds 40 mg per fortnight will not be approved.

9396M **Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 125 mL, 36 (*PKU Anamix Junior LQ*)

9397N **Amino acid formula with vitamins and minerals without phenylalanine**, Oral liquid 62.5 mL, 60 (*Lophlex LQ 10*)

Restricted benefit

Phenylketonuria

9395L **Amino acid formula with vitamins and minerals without phenylalanine and tyrosine**, Sachets 29 g, 30 (*TYR Anamix Junior*)

Restricted benefit

Tyrosinaemia

6103F **Botulinum toxin type A purified neurotoxin complex**, Lyophilised powder for I.M. injection 100 units (*Botox*)

NOTE:

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

Criteria for availability

Treatment of blepharospasm associated with dystonia, including benign blepharospasm and VIIth nerve disorders (hemifacial spasm) in patients 12 years and older

Criteria for availability

Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive

Criteria for availability

Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with botulinum toxin type A purified neurotoxin complex as a paediatric patient

Criteria for availability

Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care

Criteria for availability

Treatment of moderate to severe spasticity of the upper limbs in a cerebral palsy patient 2 years of age or older

Criteria for availability

Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 to 6 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

Contraindications to treatment include established severe contracture, known sensitivity to botulinum toxin

NOTE:

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

6293F **Clostridium botulinum type A toxin—haemagglutinin complex**, Lyophilised powder for I.M. injection 500 units (*Dysport*)

NOTE:

Arrangements to prescribe this item should be made by medical practitioners with Medicare Australia, contact telephone number 1800 700 270.

Criteria for availability

Treatment of dynamic equinus foot deformity due to spasticity in an ambulant paediatric cerebral palsy patient aged from 2 to 17 years inclusive

Criteria for availability

Continuing PBS-subsidised treatment of dynamic equinus foot deformity due to spasticity in an ambulant cerebral palsy patient 18 years of age or older who was commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient

Criteria for availability

Treatment of spasmodic torticollis, either as monotherapy or as adjunctive therapy to current standard care

Criteria for availability

Treatment of moderate to severe spasticity [defined as MAS greater than or equal to 3 using modified Ashworth scale] of the upper limb in adults following a stroke, as second line therapy when standard management has failed (e.g. physiotherapy and/or oral spasticity agents) or as an adjunct to physical therapy.

Maximum number of treatments to be authorised is 4 (total Botox and Dysport) per upper limb per lifetime. Treatment should not be initiated until 3 to 6 months post-stroke in patients who do not have established severe contracture. Treatment should be discontinued if the patient does not respond (decrease of MAS greater than 1 in at least one joint) after two treatments.

Contraindications to treatment include established severe contracture, known sensitivity to botulinum toxin

NOTE:

The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

9398P **Desmopressin acetate**, Wafer 120 micrograms (base) (*Minirin Melt*)

Authority required (STREAMLINED)

2641

Primary nocturnal enuresis in patients aged 6 years or older who are refractory to an enuresis alarm

Authority required (STREAMLINED)

2642

Primary nocturnal enuresis in patients aged 6 years or older for whom an enuresis alarm is contraindicated. The reason that an alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

NOTE:

Not to be used in preference to enuresis alarms.

Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

NOTE:

Only one application per 6 months with no more than twice the maximum quantity will be authorised for the wafers.

8849R **Escitalopram oxalate**, Oral solution 10 mg (base) per mL, 28 mL (*Lexapro*)

Restricted benefit

Major depressive disorders

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and

for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD), as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and

who has been assessed by a psychiatrist

Restricted benefit

Continuing PBS-subsidised treatment, for moderate to severe generalised anxiety disorder (GAD), of a patient commenced on escitalopram prior to 1 November 2008

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and

for whom a GP Mental Health Care Plan, as described under item 2710 of the Medicare Benefits Schedule, has been prepared

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD), as described by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria, in a patient who has not responded to non-pharmacological therapy and

who has been assessed by a psychiatrist

Restricted benefit

Continuing PBS-subsidised treatment, for moderate to severe social anxiety disorder (social phobia, SAD), of a patient commenced on escitalopram prior to 1 November 2008

9087G **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

9035M **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

9083C **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

NOTE:

Any queries concerning the arrangements to prescribe etanercept may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe etanercept should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised

biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Initial 1

Initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and

(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and

(3) have failed to achieve an adequate response to:

(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and

(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or

(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle.

NOTE:

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

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 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

9402W **Gemcitabine hydrochloride**, Solution concentrate for I.V. infusion 1000 mg (base) in 100 mL (*Gemcitabine Ebewe*)

9401T **Gemcitabine hydrochloride**, Solution concentrate for I.V. infusion 200 mg (base) in 20 mL (*Gemcitabine Ebewe*)

Authority required

Advanced breast cancer in combination with paclitaxel after failure of prior therapy which includes an anthracycline

Authority required

Advanced epithelial ovarian cancer, in combination with carboplatin, in patients who relapse more than 6 months after platinum-based therapy

Authority required

Locally advanced or metastatic non-small cell lung cancer

Authority required

Locally advanced or metastatic adenocarcinoma of the pancreas

Authority required

Locally advanced or metastatic bladder cancer, in combination with cisplatin

6496X **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

NOTE:

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe infliximab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents (adalimumab, etanercept and infliximab) for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time. Where the term 'biological agents' appears in the following NOTES and restrictions, it only refers to adalimumab, etanercept and infliximab.

From 1 August 2006, all patients will be able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial adalimumab, etanercept or infliximab without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The 5-year break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis after 1 August 2006.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for all agents except for infliximab, for which a maximum of 22 weeks will be authorised. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients.

Applications for patients who commenced treatment with etanercept prior to 17 March 2005 or adalimumab and infliximab prior to 16 March 2006, may apply for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS.

To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must re-qualify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate or sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Public and private hospital authority required

Initial 1

Initial PBS-subsidised treatment with infliximab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:

(1) have severe active psoriatic arthritis; and

(2) have received no prior PBS-subsidised biological treatment for this condition in this Treatment Cycle; and

(3) have failed to achieve an adequate response to:

(a) methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; and

(b) sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or

(c) leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity to necessitate permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of acceptable toxicities, including severity, can be found on the Medicare Australia website (www.medicareaustralia.gov.au).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(i) an active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a copy of the signed patient acknowledgement form which is included in the Supporting Information Form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment will cease if they do not demonstrate the response to treatment required to support continuation of PBS-subsidised treatment at any assessment where a response must be demonstrated.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle

9399Q **Oxycodone hydrochloride**, Tablet 15 mg (controlled release) (*OxyContin*)
9400R **Oxycodone hydrochloride**, Tablet 30 mg (controlled release) (*OxyContin*)

CAUTION:

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

NOTE:

Authorities for increased maximum quantities and/or repeats will be granted only for:

(i) chronic severe disabling pain associated with proven malignant neoplasia; or

(ii) chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-narcotic analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing narcotic analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or

(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-narcotic analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

5015Y **Oxycodone hydrochloride**, Tablet 15 mg (controlled release) (*OxyContin*) **(Dental)**

5016B **Oxycodone hydrochloride**, Tablet 30 mg (controlled release) (*OxyContin*) **(Dental)**

CAUTION:

The risk of drug dependence is high.

Restricted benefit

Chronic severe disabling pain not responding to non-narcotic analgesics

NOTE:

Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

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 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

9393J **Pramipexole hydrochloride**, Tablet 125 micrograms (*Sifrol*)
9394K **Pramipexole hydrochloride**, Tablet 250 micrograms (*Sifrol*)

CAUTION:

Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Restricted benefit

Treatment of severe primary Restless Legs Syndrome in a patient who manifests all 4 diagnostic criteria below and whose baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score is greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and

(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and

(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and

(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

Pramipexole is not PBS-subsidised for Restless Legs Syndrome secondary to other causes.

NOTE:

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

9147K **Risedronate sodium and calcium carbonate with colecalciferol**, Pack containing 4 tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms (*Actonel Combi D*)

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

NOTE:

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

9182G **Sitagliptin**, Tablet 100 mg (as phosphate monohydrate) (*Januvia*)
9180E **Sitagliptin**, Tablet 25 mg (as phosphate monohydrate) (*Januvia*)
9181F **Sitagliptin**, Tablet 50 mg (as phosphate monohydrate) (*Januvia*)

NOTE:

Sitagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone).

Authority required (STREAMLINED)

3097

Dual oral combination therapy with metformin or a sulfonylurea

Type 2 diabetes, in combination with metformin or a sulfonylurea, in a patient whose HbA1c is greater than 7% prior to initiation of sitagliptin 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 qualifying HbA1c must be documented in the patient's medical records at the time sitagliptin treatment is initiated. The HbA1c must be no more than 4 months old at the time sitagliptin treatment is initiated.

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 sitagliptin therapy, must be documented in the patient's medical records

9070J **Ziprasidone hydrochloride**, Capsule 20 mg (base) (*Zeldox*)
9071K **Ziprasidone hydrochloride**, Capsule 40 mg (base) (*Zeldox*)
9072L **Ziprasidone hydrochloride**, Capsule 60 mg (base) (*Zeldox*)
9073M **Ziprasidone hydrochloride**, Capsule 80 mg (base) (*Zeldox*)

Authority required (STREAMLINED)

1589

Schizophrenia.

Authority required (STREAMLINED)

3084

Monotherapy, for up to 6 months, of an episode of acute mania or mixed episodes associated with bipolar I disorder.

9288W **Zoledronic acid**, Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL (*Aclasta*)

Authority required

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in women 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.

Only 1 treatment each year for 3 years per patient in a lifetime will be PBS-subsidised.

Authority required

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in women with fracture due to minimal trauma.

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.

In all cases, 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.

Only 1 treatment each year for 3 years per patient in a lifetime will be PBS-subsidised.

Authority required

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in men with hip fracture due to minimal trauma.

In all cases, 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.

Only 1 treatment each year for 3 years per patient in a lifetime will be PBS-subsidised.

NOTE:

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

9390F **Zonisamide**, Capsule 100 mg (*Zonegran*)
9388D **Zonisamide**, Capsule 25 mg (*Zonegran*)
9389E **Zonisamide**, Capsule 50 mg (*Zonegran*)

Authority required (STREAMLINED)

2664

Treatment of partial epileptic seizures which are not controlled satisfactorily by other anti-epileptic drugs.

NOTES

The text of notes mentioned above:

8712M **Desmopressin acetate**, Nasal spray (pump pack) 10 micrograms per actuation, 60 actuations, 6 mL
8663Y **Desmopressin acetate**, Tablet 200 micrograms

NOTE:

Not to be used in preference to enuresis alarms.

Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

8049P **Gemcitabine hydrochloride**, Powder for I.V. infusion 200 mg (base)
9401T **Gemcitabine hydrochloride**, Solution concentrate for I.V. infusion 200 mg (base) in 20 mL

NOTE:

The powder for I.V. infusion 200 mg (base) (after reconstitution) and the solution concentrate for I.V. infusion 200 mg (base) are bioequivalent.

8050Q **Gemcitabine hydrochloride**, Powder for I.V. infusion 1 g (base)

9402W **Gemcitabine hydrochloride**, Solution concentrate for I.V. infusion 1000 mg (base) in 100 mL

NOTE:

The powder for I.V. infusion 1 g (base) (after reconstitution) and the solution concentrate for I.V. infusion 1000 mg (base) are bioequivalent.

REPATRIATION PHARMACEUTICAL BENEFITS

There are no changes to the Repatriation Pharmaceutical Benefits Schedule listings effective from 1 April 2009. New Schedules take effect on the first day of each month.