Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

SUMMARY OF CHANGES

EFFECTIVE 1 SEPTEMBER 2007

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 2007. 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 September 2007 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$5.44
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$7.48
Additional Fees (for safety net prices):	Ready-prepared	$1.01
	Extemporaneously-prepared	$1.40
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

(see under 'RESTRICTIONS' and 'NOTES' below for items where a restriction and/or a note applies)

9103D **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) [for the treatment of active ankylosing spondylitis]

9104E **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) [for the treatment of active ankylosing spondylitis] **(Diff. Max. Rpts)**

9101B **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) [for the treatment of severe active psoriatic arthritis]

9102C **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) [for the treatment of severe active psoriatic arthritis] **(Diff. Max. Rpts)**

9099X **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) [for the treatment of severe active rheumatoid arthritis]

9100Y **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*) [for the treatment of severe active rheumatoid arthritis] **(Diff. Max. Rpts)**

9097T **Cetuximab**, Solution for I.V. infusion 100 mg in 50 mL (*Erbitux*)

9098W **Cetuximab**, Solution for I.V. infusion 100 mg in 50 mL (*Erbitux*) **(Diff. Max. Qty and Rpts)**

1757L **Fluconazole**, Solution for I.V. infusion 400 mg in 200 mL (*BX*)

2261B **Lumiracoxib**, Tablet 100 mg (*Prexige*)

1166J **Phenoxybenzamine hydrochloride**, Capsules 10 mg, 30 (*Dibenyline*)

1316G **Ramipril**, Tablet 10 mg (*Tritace*)

Additions - Brands

1215Y *Comfarol Forte, WA* — **Codeine phosphate with paracetamol**, Tablet 30 mg-500 mg

3316M *Comfarol Forte, WA* — **Codeine phosphate with paracetamol**, Tablet 30 mg-500 mg **(Dental)**

8785J *Comfarol Forte, WA* — **Codeine phosphate with paracetamol**, Tablet 30 mg-500 mg **(Diff. Max. Qty)**

8400D *Hyforil, RA* — **Fosinopril sodium with hydrochlorothiazide**, Tablet 10 mg-12.5 mg

8401E *Hyforil, RA* — **Fosinopril sodium with hydrochlorothiazide**, Tablet 20 mg-12.5 mg

8561N *Meloxicam-GA, GM* — **Meloxicam**, Tablet 7.5 mg

8562P *Meloxicam-GA, GM* — **Meloxicam**, Tablet 15 mg

8331L *Omeprazole-GA, GM* — **Omeprazole**, Tablet 20 mg

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

8226Y *Onsetron, AW* — **Ondansetron**, I.V. injection 4 mg in 2 mL

1596B *Onsetron, AW* — **Ondansetron**, I.V. injection 4 mg in 2 mL **(Diff. Restriction)**

8227B *Onsetron, AW* — **Ondansetron**, I.V. injection 8 mg in 4 mL

1597C *Onsetron, AW* — **Ondansetron**, I.V. injection 8 mg in 4 mL **(Diff. Restriction)**

2289L *Sodium Valproate Sandoz, AV* — **Sodium valproate**, Tablet 200 mg (enteric coated)

2290M *Sodium Valproate Sandoz, AV* — **Sodium valproate**, Tablet 500 mg (enteric coated)

NOTES

Addition - Note

(see under 'NOTES' below for full details)

8470T **Ramipril**, Capsule 10 mg (*Prilace 10, Ramace 10 mg, Ramipril Sandoz, Ramipril Winthrop, Tritace 10 mg*)

DELETIONS

Deletions - Items

8466N **Amino acid formula with vitamins and minerals without phenylalanine**, Infant formula, powder 350 g *(Phenex-1)*

1048E **Ampicillin**, Capsule 250 mg (*Alphacin 250*)

5013W **Ampicillin**, Capsule 250 mg (*Alphacin 250*) **(Dental)**

2671N **Ampicillin**, Capsule 500 mg (*Alphacin 500*)

5014X **Ampicillin**, Capsule 500 mg (*Alphacin 500*) **(Dental)**

9032J **Lumiracoxib**, Tablet 200 mg (*Prexige*)

Deletion - Brand

2913H *Microval 28, WX* — **Levonorgestrel**, Tablets 30 micrograms, 28

ADVANCE NOTICES

Advance Notices - Deletion of Items

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

Items discontinued by the manufacturer -

1425B **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injection (human) 100 units (50 units-50 units) per mL, 10 mL (*Mixtard 50/50*)

8006J **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injections (human) 100 units (20 units-80 units) per mL, 3 mL, 5 (*Mixtard 20/80 Penfill 3 mL*)

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **January** 2008:

Items discontinued by the manufacturer -

8012Q **Oestradiol**, Transdermal patches 3.28 mg (releasing approximately 37.5 micrograms per 24 hours), 8 (*Menorest 37.5*)

8013R **Oestradiol**, Transdermal patches 4.33 mg (releasing approximately 50 micrograms per 24 hours), 8 (*Menorest 50*)

8014T **Oestradiol**, Transdermal patches 6.57 mg (releasing approximately 75 micrograms per 24 hours), 8 (*Menorest 75*)

8041F **Oestradiol**, Transdermal patches 8.66 mg (releasing approximately 100 micrograms per 24 hours), 8 (*Menorest 100*)

2163W **Thioridazine hydrochloride**, Tablet 10 mg (*Aldazine 10*)

2359E **Thioridazine hydrochloride**, Tablet 25 mg (*Aldazine 25*)

2164X **Thioridazine hydrochloride**, Tablet 50 mg (*Aldazine 50*)

2165Y **Thioridazine hydrochloride**, Tablet 100 mg (*Aldazine 100*)

Advance Notices - Deletion of Brands

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

Brand discontinued by the manufacturer -

1426C *Mixtard 30/70, NO* — **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injection (human) 100 units (30 units-70 units) per mL, 10 mL

RESTRICTIONS

The text of restrictions mentioned above:

9103D **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

Authority required

Initial 1 (new patients)
First course of PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with active ankylosing spondylitis who has radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who has not received any PBS-subsidised treatment with either adalimumab, etanercept or infliximab in this treatment cycle; AND
(a) who has at least 2 of the following:
(i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or
(ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI) [for further information on the BASMI please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; or
(iii) limitation of chest expansion relative to normal values for age and gender [for chest expansion normal values please refer to the Medicare Australia website at www.medicareaustralia.gov.au]; AND
(b) who has failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

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

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Medicare Australia website at www.medicareaustralia.gov.au.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:
(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND
(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
(iv) a signed patient acknowledgment form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis 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.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone

Authority required

Initial 2 (change or re-commencement for all patients)
Initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who, in this treatment cycle, has received prior PBS-subsidised treatment with either adalimumab, etanercept or infliximab for this condition and has not failed PBS-subsidised therapy with adalimumab.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction after 1 March 2007, the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction prior to 1 March 2007, the patient must have been assessed for response to that course following at least 4 weeks of treatment. These assessments must be provided to Medicare Australia no later than 4 weeks from the date the course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their assessment.

A maximum of 16 weeks of treatment with adalimumab will be approved under this criterion.

Where fewer than 3 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone

9104E **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

Authority required

Initial ('grandfather' patients)
Initial PBS-subsidised course of adalimumab treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who has radiographically (plain X-ray) confirmed

Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis and who was receiving treatment with adalimumab prior to 1 November 2006; AND
(a) is receiving treatment with adalimumab at the time of application; AND
(b) has not received prior PBS-subsidised treatment with infliximab or etanercept; AND
(c) whose current Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is either:
(i) less than or equal to 5 on a 0-10 scale; OR
(ii) improved by at least 2 from baseline; AND
(d) who has:
(i) an ESR measurement no greater than 25 mm per hour; or
(ii) a CRP measurement no greater than 10 mg per L; or
(iii) an ESR or CRP measurement reduced by at least 20% from pre-treatment baseline.

The BASDAI assessment and ESR and/or CRP measurements provided must be no more than 1 month old at the time of application. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

Authority applications must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the following:
(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
(ii) a completed BASDAI Assessment Form [www.medicareaustralia.gov.au]; and
(iii) a signed patient acknowledgment form included in the supporting information form. Completion of this form declares that the patient understands and acknowledges that PBS-subsidised treatment with the TNF-alfa antagonists (adalimumab, etanercept or infliximab) for ankylosing spondylitis 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.

The assessment of the patient's response to this initial course of therapy must be made within the 4 weeks prior to completion of the course in order to ensure continuity of treatment.

A patient ceasing treatment or swapping to an alternate agent and wishing to demonstrate a response to treatment, must be assessed no earlier than 12 weeks from the commencement of PBS-subsidised treatment. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone.

Patients may only qualify for PBS-subsidised treatment under this criterion once

Authority required

Continuing treatment for all patients
Continuing PBS-subsidised treatment, by a rheumatologist, of an adult with a documented history of active ankylosing spondylitis who:
(a) has demonstrated a response to treatment with adalimumab; and
(b) whose most recent course of PBS-subsidised therapy in this treatment cycle was with adalimumab.

Response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.

For a 'grandfather' patient who does not have baselines prior to commencing treatment with a TNF-alfa antagonist, see Note 5 for a definition of response to treatment.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The first application for continuing treatment following an initial treatment course must be made following a minimum of 12 weeks of treatment with adalimumab.

Applications for continuing treatment must be made in writing and should be posted to Medicare Australia no less than 2 weeks prior to the completion of the current treatment course.

Written applications for authorisation must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes a completed BASDAI Assessment Form with certification by the prescriber and the patient that the patient did not have access to their baseline BASDAI at the time of their continuing treatment assessment.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone

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

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 with a record of rheumatoid factor negative status within the last 12 months; 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.

Patients must have had the psoriatic component of their disease confirmed by a dermatologist or by biopsy at any time.

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

Authority required

Initial 2
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 a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and
(2) have received prior PBS-subsidised biological treatment for this condition in this Treatment Cycle and are eligible to receive further biological therapy; and
(3) have not failed treatment with adalimumab during the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised adalimumab treatment within this Treatment Cycle and who wish to re-commence adalimumab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment has been submitted to Medicare Australia within 1 month of cessation of treatment.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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)].

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.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

9102C **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

Authority required

Initial 3
Initial PBS-subsidised supply for continuing treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults who:
(1) have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status within the last 12 months; and
(2) were receiving treatment with adalimumab prior to 16 March 2006; and
(3) have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with adalimumab.

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)]; 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.

A maximum of 24 weeks of treatment with adalimumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 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.

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of psoriatic arthritis, of adults:
(1) who have a documented history of severe active psoriatic arthritis with a record of rheumatoid factor negative status; and
(2) whose most recent course of PBS-subsidised biological agent for this condition in the current Treatment Cycle was with adalimumab; and
(3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab.

An adequate response to treatment with adalimumab is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— 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).

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)].

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 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.

Once patients fail to respond to treatment with 3 biological agents, they are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle

9099X **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

Authority required

Initial 1 (new patients)
Application for initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
(c) have failed to achieve an adequate response to the following treatments:
(i) methotrexate at a dose of at least 20 mg weekly; and
(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
(iii) a minimum of 3 months' treatment with:
— leflunomide alone; or
— leflunomide in combination with methotrexate; or
— cyclosporin.

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 necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted 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) a total 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 Rheumatoid 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 signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

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).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

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. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial 2 (change or re-commencement)
Application for an initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with adalimumab within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

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).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

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. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

9100Y **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with adalimumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with adalimumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— 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).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 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).

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

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. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a

PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

9097T **Cetuximab**, Solution for I.V. infusion 100 mg in 50 mL (*Erbitux*)

Authority required

Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx for the week prior to radiotherapy, where cisplatin is contraindicated according to the TGA-approved Product Information

Authority required

Initial treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is not tolerated

9098W **Cetuximab**, Solution for I.V. infusion 100 mg in 50 mL (*Erbitux*) **(Diff. Max. Qty and Rpts)**

Authority required

Continuing treatment of stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx, in combination with radiotherapy, where cisplatin is either contraindicated or not tolerated

1757L **Fluconazole**, Solution for I.V. infusion 400 mg in 200 mL (*BX*)

Authority required

Treatment of cryptococcal meningitis in patients unable to take or tolerate amphotericin

Authority required

Maintenance therapy in patients with cryptococcal meningitis and immunosuppression

Authority required

Treatment of oropharyngeal candidiasis in immunosuppressed patients

Authority required

Treatment of oesophageal candidiasis in immunosuppressed patients

Authority required

Secondary prophylaxis of oropharyngeal candidiasis in immunosuppressed patients

Authority required

Treatment of serious and life-threatening candida infections in patients unable to tolerate amphotericin

2261B **Lumiracoxib**, Tablet 100 mg (*Prexige*)

Restricted benefit

Symptomatic treatment of osteoarthritis

1166J **Phenoxybenzamine hydrochloride**, Capsules 10 mg, 30 (*Dibenyline*)

Restricted benefit

Phaeochromocytoma

Restricted benefit

Neurogenic urinary retention

NOTES

The text of notes mentioned above:

Adalimumab

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:

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.

9103D **Adalimumab,** Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)
9104E **Adalimumab,** Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

NOTE:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab) and the interleukin-1 inhibitor (anakinra).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised infliximab, anakinra and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

From 1 August 2007, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 August 2007 is considered to be in their first Cycle as of 1 August 2007.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next Cycle.

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 August 2007 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of more than 5 years, may commence a new Treatment Cycle.

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2007.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this Treatment Cycle and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab and anakinra, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 August 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) 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.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these time frames, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same Treatment Cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same Treatment Cycle.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives 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.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

NOTE:

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application 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.

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

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab.

From 1 August 2007, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

9101B **Adalimumab,** Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)
9102C **Adalimumab,** Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

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 either methotrexate or sulfasalazine, 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.

9099X **Adalimumab,** Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

9100Y **Adalimumab,** Injection 40 mg in 0.8 mL pre-filled pen (*Humira*)

NOTE:

TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and infliximab for adult patients with active ankylosing spondylitis. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab, etanercept and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 TNF-alfa antagonists at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised

TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 March 2007.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for etanercept and adalimumab and 18 weeks of treatment for infliximab.

From 1 March 2007, a patient must be assessed for response to any course of initial PBS-subsidised 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, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy 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, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap to an alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they

cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives 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, an application for a patient who wishes to swap to an alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program. However, this is not required for any subsequent BASDAI results for these patients, nor for patients who were 'grandfathered' on to TNF-alfa antagonist treatment.

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.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.

A patient who commenced treatment with adalimumab for active ankylosing spondylitis prior to 1 November 2006 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.

Where pre-TNF-alfa antagonist treatment baselines cannot be provided, the following criteria must be met to demonstrate a response to treatment:The BASDAI score must be either:

(i) no more than 20% greater than the score included in the initial application for PBS-subsidised treatment; or

(ii) no greater than 2.

AND

One of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new

patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

9097T **Cetuximab,** Solution for I.V. infusion 100 mg in 50 mL *(Erbitux)*

Note:

No applications for repeats will be authorised.

9098W **Cetuximab,** Solution for I.V. infusion 100 mg in 50 mL *(Erbitux)* **(Diff. Max. Qty and Rpts)**

Note:

A maximum lifetime supply for this indication is limited to a maximum of 8 treatments per site and to 10 treatments per site.

2261B **Lumiracoxib,** Tablet 100 mg *(Prexige)*

Note:

The use of lumiracoxib for the treatment of the following conditions is not subsidised through the PBS:

(a) acute pain;

(b) soft tissue injury;

(c) arthrosis without an inflammatory component.

Note:

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

1316G **Ramipril,** Tablet 10 mg *(Tritace)*

8470T **Ramipril,** Capsule 10 mg (*Prilace 10, Ramace 10 mg, Ramipril Sandoz, Ramipril Winthrop, Tritace 10 mg*)

Note:

The ramipril 10 mg tablets and capsules are bioequivalent.

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 September 2007 and all previous issues are cancelled.

New Schedules take effect on the first day of each month.

SUMMARY OF CHANGES

For 1 September 2007 there are no changes to the Repatriation Pharmaceutical Benefits Scheme listings.