**EFALIZUMAB**, injection set containing 4 vials powder for injection 125 mg and 4 pre-filled syringes solvent 1.3 mL, Raptiva®, Serono Australia Pty Ltd

NOTE:
Any queries concerning the arrangements to prescribe efalizumab may be directed to Medicare Australia on 1800 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe efalizumab should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

**Authority required**

**Initial treatment (new patients – whole body):**
Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:
(a) have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; and
(b) have signed a patient acknowledgement form indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(c) who have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least three of the following four treatments:
   (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or
   (ii) methotrexate at a dose of 10 – 15 mg weekly for at least 6 weeks; and/or
   (iii) cyclosporin at a dose of 2 – 5 mg/kg/day for at least 6 weeks, and/or
   (iv) acitretin at a dose of 0.4mg/kg/day for at least 6 weeks.

If treatment with any one of the above-mentioned therapies is contraindicated according to the TGA-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant periods of use, the patient is exempted from demonstrating an inadequate response to that particular agent(s) only. Details of the contraindication or intolerance, including the degree of toxicity, must be provided at the time of application. Details on acceptable contraindications and toxicities, including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin can be found on the Medicare Australia website (www.medicareaustralia.gov.au)

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:
(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than one month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than one month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than one month old at the time of application.

Patients for whom a PASI assessment for any prior course of treatment, where that course of treatment was completed prior to 10 November 2005, is not available, may contact Medicare Australia on 1800 242 679 for advice.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form;
(b) a completed Efalizumab PBS Authority Application– Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) ] which includes the following:
   (i) a copy of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and whole body area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
   (ii) details of previous phototherapy and systemic drug therapy (dosage (where applicable), date of commencement and duration of therapy); and
   (iii) a copy of the signed patient acknowledgement form

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

Where fewer than 3 repeats are requested at the time of the authority 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

The assessment of the patient’s response to this 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. Applications for continuing treatment should be made prior to the completion of this course to ensure continuity of treatment for those patients who meet the continuation criterion.

Injection set containing 4 vials powder for injection 125mg and 4 pre-filled syringes of solvent 1.3 mL.

Maximum quantity 1
Number of repeats 3

NOTE: No applications for increased repeats will be authorised.
Initial treatment (Grandfather patients – whole body):
Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:
(a) have a documented history of severe chronic plaque psoriasis and were receiving treatment with efalizumab prior to 10 November 2005; and
(b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with efalizumab; and
(c) have signed a patient acknowledgement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body); and
(d) have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab (whole body).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form;
(b) a completed Efalizumab PBS Authority– Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) ] which includes the following:
   (i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams including the date of the assessment of the patient’s condition at baseline (prior to initiation of efalizumab therapy) and the most recent PASI assessment [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
   (ii) details of previous phototherapy and systemic drug therapy (dosage (where applicable), date of commencement and duration of therapy); and
   (iii) a copy of the signed patient acknowledgement form

The most recent PASI assessment must be no more than one month old at the time of application.

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

Where fewer than 5 repeats are requested at the time of 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient’s response to this initial PBS-subsidised course of therapy must be made within 4 weeks prior to completion of this course in order to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

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

Injection set containing 4 vials powder for injection 125mg and 4 pre-filled syringes of solvent 1.3 mL.
Maximum quantity  1  
Number of repeats  5  

NOTE: No applications for increased repeats will be authorised.

Continuing treatment (whole body):
Continuing PBS-subsidised treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:  
(a) have a documented history of severe chronic plaque psoriasis; and  
(b) have demonstrated an adequate response to treatment with efalizumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more after at least 12 weeks of efalizumab treatment, compared with the pre-efalizumab treatment value.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form;  
(b) a completed Efalizumab PBS Authority Application– Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
(i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and whole body area diagrams along with the date of the assessment of the patient’s condition.

The PASI assessment must be no more than one month old at the time of application.

If the application is the first application for continuing treatment with efalizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of initial treatment.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course in order to ensure continuity of treatment for those patients who meet the continuation criterion.

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

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with efalizumab.

Patients are eligible to receive continuing efalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
Patients who fail to demonstrate an adequate response, as specified in this restriction, will not be eligible to recommence treatment with efalizumab within 12 months of the date on which treatment was ceased.

Where re-treatment with efalizumab after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with efalizumab must be included in the application.

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

Where fewer than 5 repeats are requested at the time of 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Injection set containing 4 vials powder for injection 125mg and 4 pre-filled syringes of solvent 1.3 mL.

Maximum quantity 1
Number of repeats 5

NOTE: No applications for increased repeats will be authorised.

**Initial treatment (new patients - face, hand, foot):**

Initial treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:

(a) have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

(b) have signed a patient acknowledgement form indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and

(c) have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least three of the following four treatments:

(i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or

(ii) methotrexate at a dose of 10 – 15 mg weekly for at least 6 weeks; and/or

(iii) cyclosporin at a dose of 2 – 5 mg/kg/day for at least 6 weeks; and/or

(iv) acitretin at a dose of 0.4mg/kg/day for at least 6 weeks.

If treatment with any one of the above-mentioned therapies is contraindicated according to the TGA-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant periods of use, the patient is exempted from demonstrating an inadequate response to that particular agent(s) only. Details of the contraindication or intolerance, including the degree of toxicity, must be provided at the time of application. Details on acceptable contraindications and toxicities, including severity, associated with phototherapy, methotrexate, cyclosporin and acitretin can be found on the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) )
The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
   (i) at least two of the three Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than one month following cessation of the most recent prior treatment; or
   (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than one month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than one month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than one month old at the time of application.

Patients for whom a PASI assessment for any prior course of treatment, where that course of treatment was completed prior to 10 November 2005, is not available, may contact Medicare Australia on 1800 242 679 for advice.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form;
(b) a completed Efalizumab PBS Authority Application– Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:
   (i) a copy of the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient’s condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
   (ii) details of previous phototherapy and systemic drug therapy (dosage (where applicable), date of commencement and duration of therapy); and
   (iii) a copy of the signed patient acknowledgement form

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

Where fewer than 3 repeats are requested at the time of the authority 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 16 weeks.

The assessment of the patient’s response to this 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. Applications for continuing treatment should be made prior to the completion
of this course to ensure continuity of treatment for those patients who meet the continuation criterion.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

Injection set containing 4 vials powder for injection 125mg and 4 pre-filled syringes of solvent 1.3 mL.
Maximum quantity  1
Number of repeats  3

NOTE: No applications for increased repeats will be authorised.

Initial treatment (Grandfather patients - face, hand, foot):
Initial PBS-subsidised supply for continuing treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over:
(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot and were receiving treatment with efalizumab prior to 10 November 2005; and
(b) whose disease, prior to treatment with efalizumab, was of a severity as defined in the initiation criterion included in the initial treatment restriction (new patients - face, hand, foot); and
(c) have signed a patient acknowledgement form indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot); and
(d) have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab (face, hand, foot).

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form;
(b) a completed Efalizumab PBS Authority Application – Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au) ] which includes the following:
   (i) a copy of the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s condition at baseline (prior to initiation of efalizumab therapy) and the most recent PASI assessment [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and
   (ii) details of previous phototherapy and systemic drug therapy (dosage (where appropriate), date of commencement and duration of therapy); and
   (iii) a copy of the signed patient acknowledgement form

The PASI assessment must be performed on the same affected area as assessed prior to initiation of efalizumab treatment.

The most recent PASI assessment must be no more than one month old at the time of application.
A maximum of 24 weeks of treatment with efalizumab will be authorised under this restriction.

Where fewer than 5 repeats are requested at the time of 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The assessment of the patient’s response to this initial PBS-subsidised course of therapy must be made within 4 weeks prior to completion of this course in order to ensure continuity of treatment for those patients who meet the continuation criterion included in the restriction for continuing PBS-subsidised treatment with efalizumab.

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

Injection set containing 4 vials powder for injection 125mg and 4 pre-filled syringes of solvent 1.3 mL.

Maximum quantity 1
Number of repeats 5

NOTE: No applications for increased repeats will be authorised.

**Continuing treatment (face, hand, foot)**

Continuing PBS-subsidised treatment as systemic monotherapy (i.e. not in conjunction with acitretin, methotrexate or cyclosporin) by a dermatologist for adults 18 years and over who:

(a) have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot; and

(b) have demonstrated an adequate response to treatment with efalizumab.

An adequate response to efalizumab treatment is defined as the plaque or plaques assessed prior to efalizumab treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all three of erythema, thickness and scaling, to slight or better, after at least 12 weeks of efalizumab treatment, as compared to the pre-efalizumab treatment values; or

(ii) a reduction by 75% or more in the skin area affected, after at least 12 weeks of efalizumab treatment, as compared to the pre-efalizumab treatment value.

The PASI assessment for continuing treatment must be performed on the same affected area assessed prior to initiation of efalizumab treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form;

(b) a completed *Efalizumab PBS Authority Application– Supporting Information Form* [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a copy of the Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams along with the date of the assessment of the patient’s
condition [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

The PASI assessment must be no more than one month old at the time of application.

If the application is the first application for continuing treatment with efalizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of initial treatment.

The assessment of the patient’s response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course in order to ensure continuity of treatment for those patients who meet the continuation criterion.

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

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with efalizumab.

Patients are eligible to receive continuing efalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate an adequate response, as specified in this restriction, will not be eligible to recommence treatment with efalizumab within 12 months of the date on which treatment was ceased.

Where re-treatment with efalizumab after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with efalizumab must be included in the application.

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

Where fewer than 5 repeats are requested at the time of 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 242 679 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Injection set containing 4 vials powder for injection 125mg and 4 pre-filled syringes of solvent 1.3 mL.

Maximum quantity 1
Number of repeats 5

NOTE: No applications for increased repeats will be authorised.