ETANERCEPT, injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL, Enbrel®, Wyeth Australia Pty Ltd.

Restriction yet to be finalised.

Extend the authority required listing to add the following:

Restriction:

Authority required
Initial treatment by a rheumatologist of adults with active ankylosing spondylitis who have radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis;
AND
(a) 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 HIC website at www.hic.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 HIC website at www.hic.gov.au];
AND
(b) who have documented confirmation of HLA-B27 positive status;
AND
(c) who have signed a patient acknowledgment form indicating that they understand and acknowledge that PBS-subsidised treatment with etanercept for ankylosing spondylitis will cease if the pre-determined response criteria do not support continuation of PBS-subsidised treatment;
AND
(d) who have failed to achieve an adequate response following a minimum of 3 months' total treatment with:
(i) at least 2 non-steroidal anti-inflammatory drugs (NSAIDs); AND
(ii) a concomitant appropriate exercise program.

The application must include details of the NSAIDs trialed, 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 reasons why a higher dose cannot be used.

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

The following criteria must be met in order to demonstrate failure to achieve an adequate response:
(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.

The requirement to complete a 3 month NSAID and exercise trial may be waived if the patient has had a break in etanercept therapy which is less than 12 months in duration.

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 reasons why this criterion cannot be satisfied.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the patient is exempted from demonstrating an inadequate response to the above treatment regimen. Where appropriate, evidence to support a contraindication must be provided. If adverse events of a severity necessitating permanent withdrawal develop during the relevant period of use of 2 NSAIDs, the patient may be exempted from demonstrating an inadequate response to the above treatment regimen. For details of the adverse events, including the severity, that will be accepted for the purposes of administering this restriction, please refer to the HIC website at www.hic.gov.au.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Etanercept PBS Authority Application for Initial Use in the Treatment of Ankylosing Spondylitis – Supporting Information Form [may be downloaded from the HIC website (www.hic.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 copy of the pathology report from an Approved Pathology Authority confirming the presence of HLA-B27; and
    (iii) a copy of the completed BASDAI Assessment Form [may be downloaded from the HIC website (www.hic.gov.au)]; and
    (iv) a copy of the signed patient acknowledgment form [may be downloaded from the HIC website (www.hic.gov.au)].

The patient's response to the initial course of treatment should be assessed no earlier than 4 weeks, and no later than 6 weeks, from the commencement of treatment.

Maximum quantity: 2
Repeats: 1

Authority required
Continuing PBS-subsidised treatment, by a rheumatologist, of adults with active ankylosing spondylitis who have received initial PBS-subsidised treatment of PBS-subsidised treatment with etanercept and who, at the time of application, demonstrate a response to treatment with etanercept.

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.

The same acute phase reactant measured in the first continuing treatment application must be measured in all subsequent continuing treatment applications.

A maximum of 24 weeks of treatment with etanercept will be authorised under this criterion. No applications for increased repeats will be authorised. 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.

The first application for continuing treatment should be made no earlier than 4 weeks, and no later than 6 weeks**,** from the commencement of treatment. This first authority application (completed application form only, not the authority prescription) may be faxed to the HIC on (03) 6215 5640 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The HIC will then contact the prescriber by telephone.

Second and subsequent applications for continuing treatment must be made in writing and posted to the HIC no less than 2 weeks prior to the date the next dose is scheduled, to ensure continuity of treatment.

Written applications for authorisation must include:
(a) a completed authority prescription form; and
(b) a completed Etanercept PBS Authority Application for Continuing Use in the Treatment of Ankylosing Spondylitis – Supporting Information Form [may be downloaded from the HIC website (www.hic.gov.au)] which includes the following:
    (i) a copy of the completed BASDAI Assessment Form [may be downloaded from the HIC website (www.hic.gov.au)] including 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.

Patients who fail to demonstrate a response to treatment with etanercept for ankylosing spondylitis as specified in the criteria for continuing treatment with etanercept will not be eligible to recommence treatment with this drug within 12 months of the date on which treatment was ceased.

Applications for PBS-subsidised treatment will not be authorised for patients who have failed 2 PBS-subsidised courses of treatment with etanercept.

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

Maximum quantity: 2
Repeats: 5

Authority required

Initial PBS-subsidised supply for continuing treatment by a rheumatologist of adults with active ankylosing spondylitis who have radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis;

AND

(a) who are currently receiving treatment with etanercept and were receiving treatment with etanercept prior to 1 July 2004;

AND

(b) who have documented confirmation of HLA-B27 positive status;

AND

(c) whose Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score is less than or equal to 5 on a 0-10 scale;

AND

(d) who have signed a patient acknowledgment form indicating that they understand and acknowledge that PBS-subsidised treatment with etanercept for ankylosing spondylitis will cease if the pre-determined response criteria do not support continuation of PBS-subsidised treatment;

AND

(e) who have:

(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 must be no more than 1 month old at the time of application. The same acute phase reactant measured in the first application for PBS-subsidised treatment must be measured in all subsequent continuing treatment applications.

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

(a) a completed authority prescription form; and

(b) a completed Etanercept PBS Authority Application for Initial Use in the Treatment of Ankylosing Spondylitis – Supporting Information Form [may be downloaded from the HIC website (www.hic.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 copy of the pathology report from an Approved Pathology Authority confirming the presence of HLA-B27; and

(iii) a copy of the completed BASDAI Assessment Form [may be downloaded from the HIC website (www.hic.gov.au)]; and

(iv) a copy of the signed patient acknowledgment form [may be downloaded from the HIC website (www.hic.gov.au)].

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

Up to a maximum of 5 repeats may be authorised. No applications for increased repeats will be authorised. 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.

Maximum quantity: 2
Repeats: 5

Authority required
Continuing PBS-subsidised supply for treatment by a rheumatologist of adults with active ankylosing spondylitis who were receiving treatment with etanercept prior to 1 July 2004 and who have received initial treatment with etanercept as a pharmaceutical benefit for the treatment of active ankylosing spondylitis;
AND
whose BASDAI score is no more than 20% greater than the score included in their initial application for PBS-subsidised treatment AND who have:
(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 pre-treatment baseline.

The same acute phase reactant measured in the first continuing treatment application must be measured in all subsequent continuing treatment applications.

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

Applications for continuing treatment must be made in writing and posted to the HIC no less than 2 weeks prior to the date the next dose is scheduled, to ensure continuity of treatment.

A maximum of 24 weeks of treatment with etanercept will be authorised under this criterion. Up to a maximum of 5 repeats will be authorised. No applications for increased repeats will be authorised. 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.

Applications for authorisation must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Etanercept PBS Authority Application for Continuing Use in the Treatment of Ankylosing Spondylitis – Supporting Information Form [may be downloaded from the HIC website (www.hic.gov.au)] which includes the following:
(i) a copy of the completed BASDAI Assessment Form [may be downloaded from the HIC website (www.hic.gov.au)] including 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.

Patients receiving PBS-subsidised treatment under this criterion who fail to demonstrate a response to treatment with etanercept for ankylosing spondylitis as specified will not be eligible to recommence treatment with this drug within 12 months of the date on which treatment was ceased and will be required to meet the criteria for initial treatment for new patients.

Applications for PBS-subsidised treatment will not be authorised for patients who have failed 2 PBS-subsidised courses of treatment with etanercept.

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

Maximum quantity: 2
Repeats: 5