

ANAKINRA, pre-filled syringe, 100 mg in 0.67 mL, Kineret[®], Amgen Australia Pty Ltd.

(Restriction yet to be finalised)

Restriction:

Authority Required

Initial treatment by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, in combination with methotrexate at a minimum dose of 7.5 mg weekly, of adults with severe active rheumatoid arthritis who have a record of rheumatoid factor positive status;

AND

a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the pre-determined response criteria do not support continuation of PBS-subsidised treatment;

AND

b) who have failed to achieve an adequate response to methotrexate alone, at a dose of at least 20 mg weekly;

AND

c) who have failed to achieve an adequate response to methotrexate, in combination with 2 other disease modifying anti-rheumatic drugs (DMARDs) for a minimum of 3 months;

AND

d) have subsequently failed to achieve an adequate response following a minimum of three months' treatment with:

i) leflunomide alone

or

ii) leflunomide in combination with methotrexate

or

iii) cyclosporin.

AND

e) have subsequently failed to achieve a response following initial treatment with one or more TNF alfa antagonists within the interchangeability period permitted for biologic DMARD therapy.

Initial treatment with anakinra must take place within the interchangeability period permitted for biologic DMARD therapy. A suitable wash-out period in accordance with the pharmacokinetics for the preceding TNF-alfa antagonist is recommended.

If treatment with any of the above-mentioned drugs is contra-indicated according to the relevant TGA-approved product information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, the patient is exempted from demonstrating an inadequate response to the above treatment regimens. Details of the contraindication or intolerance, including the degree of toxicity, must be provided at the time of application. If treatment with a TNF alfa antagonist is not tolerated, treatment with anakinra may commence immediately following a suitable wash-out period as appropriate.

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP), 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 four active joints from the following list:

- 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 in writing and must include sufficient information to determine the patient's eligibility according to the above criteria. The date of joint assessment must be provided.

Where fewer than 2 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 3 months of treatment may be requested by telephone. Under no circumstances will telephone approvals be granted for initial or continuing authority applications, or for treatment that would otherwise extend the initial biologic treatment period beyond 3 months.

The assessment of the patient's response to the initial course of treatment should be made after at least 8 weeks of treatment so that there is adequate time for a response to be demonstrated

Applications for continuing treatment with anakinra should be made prior to the completion of 12 weeks of treatment to ensure continuity for those patients who meet the criteria.

Maximum Qty: 28

Repeats: 2

Authority Required

Continuing PBS-subsidised treatment by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis in combination with methotrexate at a minimum dose of 7.5 mg weekly, of adults with severe active rheumatoid arthritis who, at the time of application demonstrate an adequate response to treatment with anakinra as manifested by:

an ESR no greater than 25 mm per hour or a CRP no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND 1 or more of the following

i) an active joint count of less than 10 active (swollen and tender) joints

OR

ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline,

OR

iii) a reduction in the number of the following 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 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).

All authority applications for continuing treatment with anakinra must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of assessment of the patient must be provided.

Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with anakinra, will not be eligible to re-commence treatment with PBS subsidised anakinra within 5 years of the date on which treatment was ceased.

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

Authority Required

Initial PBS-subsidised supply for continuing treatment by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, in combination with methotrexate at a minimum dose of 7.5mg weekly, of adults with severe active rheumatoid arthritis who have a record of rheumatoid factor positive status and who were receiving treatment with anakinra prior to 1 July 2004;

AND

- (a) who would have qualified under the initial criteria for PBS subsidy

AND

- (b) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the pre-determined response criteria do not support continuation of PBS-subsidised treatment

AND

- (c) who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with anakinra.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment of the patient must be provided.

Maximum Quantity: 28

Repeats: 5
