

17 November 2003

To All Interested Parties*By facsimile (2 pages)***Proposed access criteria for etanercept (Enbrel)**

Following our consultation letters of 15 and 16 October 2003, regarding a provisional agreement with Wyeth (NZ) Limited involving the listing of etanercept (Enbrel) for juvenile rheumatoid arthritis, PHARMAC has now finalised proposed access criteria. It is proposed that etanercept be listed on the Pharmaceutical Schedule from or as soon as possible after, 1 January 2004 subject to final approval by the PHARMAC Board, or the Chief executive under delegated authority.

The proposed Special Authority Criteria have been based on the Australian access criteria for etanercept (Enbrel). PHARMAC has sought the advice of the Pharmacology and Therapeutics Advisory Committee (PTAC) along with the specialists in the area of paediatric rheumatology. The proposed Special Authority Criteria for access to etanercept (Enbrel) are as follows:

Initial Application

1. Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.
2. Patient is less than 18 years of age at commencement of treatment.
3. Patient has had severe active polyarticular course Juvenile Idiopathic Arthritis (JIA) for 6 months duration or longer.
4. Patient has tried and not responded to an adequate therapeutic trial of at least three months of each of the following regimens:
 - a. oral or parenteral methotrexate at a dose of 10-20mg/m² weekly in combination with oral corticosteroids (prednisone \geq 0.25 mg/kg);
 - b. oral or parenteral methotrexate (10-20mg/m² weekly) in combination with one other disease-modifying agent.
5. Patient has persistent symptoms of poorly-controlled and active disease:
 - a. a joint count of at least 20 active joints; or
 - b. at least four active joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
 - c. physician's global assessment indicating severe disease.
6. The patient or their legal guardian consents to details of their treatment being held on a central registry and has signed a consent form outlining conditions of ongoing treatment.
7. Application by named specialists only.
8. Initial applications are valid for 16 weeks.

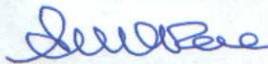
Reapplications

1. Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.
2. Patient's response to treatment:

- a. first reapplication following 12 weeks of treatment the patient should have a \geq 50% decrease in active joint count and an improvement in physician's global assessment from baseline;
- b. further reapplications must demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.
3. Reapplications by named specialists.
4. Reapplications are valid for 6 months unless patient fails to meet these criteria at any time during treatment.

If you have comments to make on the proposed access criteria and would like those comments to be considered by the PHARMAC Board, or the Chief Executive under delegated authority, please forward them to Adam McRae at PHARMAC by **5pm Friday, 28 November 2003**. All comments submitted by this date will be considered.

Yours sincerely



Adam McRae
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