

26 April 2007

To All Pharmaceutical Suppliers, Hospital Pharmacists, Medical Groups and Interested Parties

**Notification of listing of sirolimus (Rapamune) on the Pharmaceutical Schedule and amendment to listing of etanercept (Enbrel) on the Pharmaceutical Schedule.**

PHARMAC is pleased to advise that the PHARMAC Board has approved the proposal to list sirolimus (Rapamune) and etanercept (Enbrel) in Sections B and H of the Pharmaceutical Schedule. This means that:

**Etanercept:**

- The price and subsidy for etanercept in Section B, and the price in Part II of Section H will be amended from 1 July 2007 as follows:

Table 1.

| Pharmaceutical | Form      | Strength | Pack Size | Brand  | Current Price and Subsidy | New Price and Subsidy |
|----------------|-----------|----------|-----------|--------|---------------------------|-----------------------|
| etanercept     | Injection | 25 mg    | 4         | Enbrel | \$899.96                  | \$949.96              |

Note: Prices are ex-manufacturer, exclusive of GST

- Community usage of etanercept will be subject to a confidential rebate.
- The Special Authority for etanercept in Section B will be amended as follows from 1 July 2007 (changes in bold and strikethrough):

Initial application only from a named specialist **or a rheumatologist**. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Patient **diagnosed with Juvenile Idiopathic Arthritis (JIA)** ~~is less than 18 years of age at commencement of treatment;~~ and
- 3 Patient has had severe active polyarticular course ~~Juvenile Idiopathic Arthritis (JIA)~~ for 6 months duration or longer; and
- 4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20mg/m<sup>2</sup> **or at maximum tolerated dose**) weekly in combination with oral corticosteroids (prednisone 0.25 mg/kg **or at maximum tolerated dose**); and
- 5 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-15mg/m<sup>2</sup> weekly **or at maximum tolerated dose**) in combination with one other disease-modifying agent; and

- 6 Both:
- 6.1 Either:
- 6.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 active, swollen, tender joints; or
- 6.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
- 6.2 Physician's global assessment indicating severe disease; and
- 7 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.

Note:

A patient declaration form [http://www.pharmac.govt.nz/special\\_authority\\_forms/SA0667-declaration.pdf](http://www.pharmac.govt.nz/special_authority_forms/SA0667-declaration.pdf) must be signed by the legal guardian of the patient and the prescriber in the presence of a witness (over 18 years of age).

Renewal only from a named specialist **or a rheumatologist**. Approvals valid for 6 months for applications meeting the following criteria:

Both:

8 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

9 Either:

- 9.1 Following 4 months initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
- 9.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

## Sirolimus

- Sirolimus will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 July 2007 as follows:

Table 2.

| Pharmaceutical | Form        | Strength  | Pack Size | Brand    | Price and Subsidy |
|----------------|-------------|-----------|-----------|----------|-------------------|
| sirolimus      | Tablet      | 1 mg      | 100       | Rapamune | \$813.00          |
| sirolimus      | Tablet      | 2 mg      | 100       | Rapamune | \$1,626.00        |
| sirolimus      | Oral liquid | 1 mg / ml | 60 ml     | Rapamune | \$487.80          |

Note: Prices are ex-manufacturer, exclusive of GST

- Sirolimus will be listed in the 'Oncology Agents and Immunosuppressants – Other Immunosuppressants' section of Section B of the Pharmaceutical Schedule.
- Community and hospital usage of sirolimus would be subject to a confidential rebate.

- Sirolimus will be subject to the following Special Authority restrictions in Section B of the Pharmaceutical Schedule:

Initial application from any medical practitioner. Approvals valid without further renewal unless notified. Approvals valid for rescue therapy where patient is an organ transplant recipient.

Note: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following: GFR<30 ml/min; or Rapidly progressive transplant vasculopathy; or Rapidly progressive obstructive bronchiolitis; or HUS or TTP; or Leukoencephalopathy; or Significant malignant disease

We thank all those who submitted responses to consultation.

Yours sincerely



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