CONSULTATION

PHARMAC
Pharmaceutical Management Agency

4 April 2014

Proposal to fund adalimumab and etanercept for the treatment of pyoderma gangrenosum

PHARMAC is seeking feedback on a proposal to amend the listing of two tumour necrosis factor (TNF) inhibitors, etanercept and adalimumab, to include funding for the treatment of pyoderma gangrenosum.

In summary, this proposal would result in access to etanercept and adalimumab being widened via Special Authority to include the treatment of pyoderma gangrenosum from 1 June 2014.

Details of the proposal are set out on the following page.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 17 April 2014** to:

Bronwyn Hale
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: Bronwyn.hale@pharmac.govt.nz
Fax: 04 460 4995
Post: PO Box 10 254, Wellington 6143

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

Details of the proposal

Etanercept and adalimumab

- From 1 June 2014 the Special Authorities for etanercept and adalimumab in Section B (community) of the Pharmaceutical Schedule would be amended to include the indication of pyoderma gangrenosum as follows:

> Special Authority:
>
> **Initial application** – only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
>
> All of the following;
>
> 1. Patient has pyoderma gangrenosum*; and
> 2. Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response; and
>
> Either;
>
> 3. Patient is commenced on adalimumab at 40mg per week on alternate weeks up to a maximum of 3 x 40mg doses: or
> 4. Patient is commenced on etanercept at 50mg per week up to a maximum of 3 x 50 mg doses.
>
> **Renewal** – only from a dermatologist or a Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
>
> All of the following;
>
> 1. Either:
> 1.1 The applicant is a dermatologist: or
> 1.2 The applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax of recommendation; and
> 2. Patient has shown clinical improvement; and
> 3. Patient continues to require treatment; and
>
> Either;
>
> 4. Patient is commenced on adalimumab at 40mg per week on alternate weeks up to a maximum of 3 x 40mg doses: or
> 5. Patient is commenced on etanercept at 50mg per week up to a maximum of 3 x 50 mg doses.
>
> * Note: Indications marked with * are Unapproved Indications (refer to Section A: General Rules, Part I (Interpretations and Definitions) and Part IV (Miscellaneous Provisions) rule 4.6).

- From 1 June 2014 the restrictions for etanercept and adalimumab in Part II of Section H (hospital) of the Pharmaceutical Schedule would be amended to include the indication of pyoderma gangrenosum as follows:

Initiation – pyoderma gangrenosum
Dermatologist
Re-assessment required after 4 months
All of the following;

1. Patient has pyoderma gangrenosum*; and
2. Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response; and

Either;

3. Patient is commenced on adalimumab at 40mg per week on alternative weeks up to a maximum of 3 x 40mg dose: or
4. Patient is commenced on etanercept at 50mg per week up to a maximum of 3 x 50 mg dose.

Continuation– pyoderma gangrenosum
Re-assessment required after 4 months
Dermatologist

All of the following;

1. Patient has shown clinical improvement; and
2. Patient continues to require treatment; and

Either;

3. Patient is commenced on adalimumab at 40mg per week on alternative weeks up to a maximum of 3 x 40mg doses: or
4. Patient is commenced on etanercept at 50mg per week up to a maximum of 3 x 50 mg doses.

* Note: Indications marked with * are Unapproved Indications (refer to Section A: General Rules, Part I (Interpretations and Definitions) and Part IV (Miscellaneous Provisions) rule 4.6)

Background

Pyoderma gangrenosum is a rare non-infectious neutrophillic dermatosis, which presents clinically with painful ulcers of various depth and size. The incidence is generally considered to be 3 -10 new patients per million population per year. Therapies for treatment include corticosteroids, immunosuppressive agents and biologic agents.

In November 2012 the Pharmacology and Therapeutics Advisory Committee (PTAC) recommended that biological treatments be funded to treat pyoderma gangrenosum via Special Authority criteria. You can find a record of the minutes of the meeting on PHARMAC's website by following this link:

http: www.pharmac.health.nz assets ptac-minutes-2012-11.pdf.

In summary, PTAC recommended that biologic treatment should be funded for pyoderma gangrenosum that is refractory to conventional treatments.

It is estimated that up to 12 additional patients per year would access funded adalimumab or etanercept if the proposal is progressed.