NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

17June 2014

Decision to widen access and fund adalimumab and etanercept for the treatment of pyoderma gangrenosum

PHARMAC is pleased to announce the approval of a proposal to fund adalimumab and etanercept to treat pyoderma gangrenosum in the community and hospital setting. This was the subject of a consultation letter dated 4 April 2014. The consultation letter can be found at

http://www.pharmac.health.nz/assets/consultation-2014-04-04-tnf-inhibitors.pdf

Summary of the decision

This decision means that funded access to etanercept and adalimumab will be widened via Special Authority in Section B and restrictions in Section H of the Pharmaceutical Schedule to include the treatment of pyoderma gangrenosum from 1 July 2014.

Details of the decision

From 1 July 2014 the listing of the two tumour necrosis factor (TNF) inhibitors, etanercept and adalimumab, will be amended in Section B of the Pharmaceutical Schedule to include the treatment of pyoderma gangrenosum as follows:

> **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*;
> 2. Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, cyclosporine, azathioprine, or methotrexate) and not received an adequate response; and
> 3. A maximum of 4 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. Patient has shown clinical improvement;
> 2. Patient continues to require treatment; and
> 3. A maximum of 4 doses.
>
> Note: Indications marked with * are Unapproved Indications (refer to Section A: General Rules, Part I 1.1 (Interpretations and Definitions) and Part V (Miscellaneous Provisions) rule 5.5).

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

From 1 July 2014 the listing of the two tumour necrosis factor (TNF) inhibitors, etanercept and adalimumab, will be amended in Part II of Section H of the Pharmaceutical Schedule to include the treatment of pyoderma gangrenosum as follows:

Indication - pyoderma gangrenosum
Dermatologist

All of the following;

1. Patient has pyoderma gangrenosum*;
2. Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, cyclosporine, azathioprine, or methotrexate) and not received an adequate response; and
3. A maximum of 4 doses.

Renewal – pyoderma gangrenosum*
Dermatologist

All of the following;

1. Patient has shown clinical improvement;
2. Patient continues to require treatment; and
3. A maximum of 4 doses.

Note: Indications marked with * are Unapproved Indications (refer to Part I: General Rules (Interpretations and Definitions) and (Miscellaneous Provisions) rule 23).

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by Thursday 17 April were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
A three month stand down period would be too long to deny treatment to a patient.	Alternative funded treatment options are available for patients to try initially. This criteria enables access to adalimumab and etanercept if the patient has not responded to first line therapy. In November 2012 PTAC recommended biological treatments be listed for the treatment of this indication in the pharmaceutical
Multiple applications for treatment should be possible as this is a chronic disorder	Noted. The application enables renewals to continue patient treatment, following assessment of patient meeting criteria.
Original packs for either of these two treatments come as packs of two or four therefore a dosing regimen of three doses would cause wastage.	The criteria have been changed to enable a maximum of 4 doses which will accommodate the original pack size.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.