

10 September 2008

Proposal to remove prescriber restrictions on acitretin and isotretinoin

PHARMAC is seeking feedback on a proposal to remove the prescriber restrictions on acitretin and isotretinoin. In addition it is proposed that isotretinoin would be subject to a Special Authority.

This letter outlines the proposal and how you can provide your feedback on it.

Proposal Summary

Acitretin is a retinoid for oral treatment of severe cases of psoriasis and of disorders of keratinisation. Isotretinoin is an oral medication used for the treatment of severe acne and acne resistant to other forms of treatment.

Currently, in order to receive acitretin and isotretinoin fully funded, all prescriptions need to be written by a dermatologist.

PHARMAC is proposing to remove the “dermatologist only” prescriber restriction on acitretin and isotretinoin in Section B of the Pharmaceutical Schedule. In addition, it is proposed that isotretinoin would be replaced with a Special Authority that could be applied for by any relevant practitioner who is credentialed in the use of isotretinoin and whose scope of practice includes its use, as detailed on the following pages, with effect from 1 December 2008.

Why are we proposing this?

The current specialist restrictions for acitretin and isotretinoin result in equity of access problems particularly for people on low incomes and those in rural areas who may have limited access to specialists. The proposal would make these products more accessible to patients requiring these products.

The purpose of the proposed Special Authority would be to make funded isotretinoin more easily available while ensuring that the safety and clinical risks associated with prescribing isotretinoin are taken into account.

We acknowledge that the prescribing of isotretinoin requires careful consideration. We consider that in general the responsibility for this lies with the prescriber. However, in this particular instance we consider the risks associated with isotretinoin use and the particular patient population mean that the use of a Special Authority could be helpful. While we appreciate any feedback that you may have, we would particularly like to receive feedback regarding this proposed method for managing risk.

Feedback sought

We welcome your feedback on this proposal. To provide feedback on this proposal please submit it by **5 pm, Friday 3 October 2008** to:

Mike Bignall
Therapeutic Group Manager
PHARMAC
PO Box 10-254, Wellington 6143

Email: mike.bignall@pharmac.govt.nz

Fax: (04) 460 4995

We also invite any person or group to contact PHARMAC should you wish to have a meeting to discuss this consultation.

What will happen then?

All of the submissions we receive before the deadline will be considered by PHARMAC's Board (or Chief Executive, acting under delegated authority) when making a decision on whether to implement this proposal.

If the proposal is approved, it is anticipated that the proposed changes would take effect from 1 December 2008.

Details of the proposal

Proposed amendments to the Pharmaceutical Schedule are as follows (deletions shown in strikethrough, additions in **bold**):

- ACITRETIN – ~~Hospital pharmacy [HP3] – Specialist prescription. Specialist must be a dermatologist~~
Cap 10 mg
Cap 25 mg
- ISOTRETINOIN – ~~Hospital pharmacy [HP3] – Specialist prescription. Specialist must be a dermatologist~~
Cap 10 mg
Cap 20 mg

Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1. Patient has had an adequate trial on other available treatments and has failed these treatments or is contraindicated.**
- 2. Applicant is credentialed in the use of isotretinoin.**

Note: Credentialed is defined using the Medsafe datasheet that states that isotretinoin should only be prescribed by physicians who are experienced in the use of systemic retinoids, preferably dermatologists, and understand the risk of teratogenicity if isotretinoin is used during pregnancy.

Renewal application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1. Patient has trialled isotretinoin and is continuing to derive benefit from treatment.**
- 2. Applicant is credentialed in the use of isotretinoin.**

Note: Credentialed is defined using the Medsafe datasheet that states that isotretinoin should only be prescribed by physicians who are experienced in the use of systemic retinoids, preferably dermatologists, and understand the risk of teratogenicity if isotretinoin is used during pregnancy.

Background

The Pharmacology and Therapeutics Advisory Committee (PTAC) has considered the use of prescriber restrictions in the dermatology therapeutic group of the Pharmaceutical Schedule. PTAC recommended that if the specialist restriction were to be removed, that a Special Authority should be applied to help draw attention to the clinical risks around pregnancy and suicidal ideation.

PTAC considered that isotretinoin should be able to be prescribed by appropriately trained GPs, and that PHARMAC staff should develop a course to achieve this in conjunction with other relevant organisations.

Education and Training

If this proposal is approved training opportunities would be made available by PHARMAC over a number of sessions through PHARMAC's Seminar Series. In addition, educational material would be developed and circulated widely.

In line with previous advice from PTAC we have worked with BPAC (Best Practice Advocacy Centre) to develop a decision support tool. We would recommend the use of this or other appropriate decision support tools should the restriction for isotretinoin be removed.

We also anticipate that the relevant medical bodies would develop accredited courses for the use of isotretinoin.

Decision support systems

A decision support tool is an application that provides clinicians with recommendations for appropriate treatment of patients which are customised to the condition and history of the patient. A decision support tool:

- provides direct links to the latest evidence based practice;
- provides access to patient information that is specific, relevant and suitable, in a printable format ready for patients;
- can generate prescriptions with direct links to prescribing information;
- can apply for Special Authorities electronically; and
- can pre-populate known clinical information into referrals.

BPAC already provides a wide range of modules that are currently being used amongst healthcare professionals and an anti-acne module is soon to be rolled out nationwide. This module integrates with the practice's Patient Management System (PMS).

Where does the information included in decision support tools come from?

The BPAC decision support tool is based on current New Zealand guidelines and best practice. Its contents is similar to the contents of international resources, Clinical Evidence and the British National Formulary, it also links to reputable websites such as Dermnet.

How does it work?

Decision support tools can run on their own on the Internet, but are often run on servers using Microsoft's Internet Information Server (IIS) which allows these servers to be located on the Internet, within a VPN or even located within a practice network. Communication between the PMS and the decision support server is encrypted and not open to eavesdropping by using SSL client certificates. BPAC's security model is based on existing Health Standards.

Assistance

Ongoing support with the use of the BPAC decision support tool is provided through BPAC's 0800 support line.