

19 December 2008

## Changes to prescriber restrictions for acitretin and isotretinoin approved

PHARMAC is pleased to announce changes to the prescribing restrictions applying to acitretin and isotretinoin. The changes mean that vocationally registered dermatologists, vocationally registered general practitioners, and nurse practitioners working in a relevant scope of practice can now prescribe acitretin and isotretinoin via Special Authority.

If you have any queries about this funding decision you can call our toll free number on 0800 66 00 50 (9am to 5pm, Monday to Friday).

### Details of the decision

The Hospital pharmacy [HP3] – Specialist prescription restriction, where the Specialist must be a dermatologist that currently applies to acitretin and isotretinoin will be removed from 1 March 2009. They will be replaced by the following Special Authorities which will also apply from 1 March 2009:

#### ***Acitretin***

##### **SA#### Special Authority for Subsidy**

Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- 2 Applicant has an up to date knowledge of the treatment options for psoriasis and of disorders of keratinisation and is aware of the safety issues around acitretin and is competent to prescribe acitretin; and
- 3 Patient has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and the applicant has ensured that, for female patients, the possibility of pregnancy has been excluded prior to the commencement of the treatment and that (where applicable) the patient is informed that she must not become pregnant during treatment and for a period of two years after the completion of the treatment.

Renewal from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- 2 Applicant has an up to date knowledge of the treatment options for psoriasis and of disorders of keratinisation and is aware of the safety issues around acitretin and is competent to prescribe acitretin; and
- 3 Patient has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and the applicant has ensured that, for female patients, the possibility of pregnancy has been excluded prior to the commencement of the treatment and that (where applicable) the patient is informed that she must not become pregnant during treatment and for a period of two years after the completion of the treatment.

## **Isotretinoin**

### **SA#### Special Authority for Subsidy**

Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Patient has had an adequate trial on other available treatments and has failed these treatments or these are contraindicated; and
- 2 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- 3 Applicant has an up to date knowledge of the treatment options for acne and is aware of the safety issues around isotretinoin and is competent to prescribe isotretinoin; and
- 4 Patient has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and the applicant has ensured that, for female patients, the possibility of pregnancy has been excluded prior to the commencement of the treatment and that (where applicable) the patient is informed that she must not become pregnant during treatment and for a period of one month after the completion of the treatment.

#### Note

Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

Renewal from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Patient has had an adequate trial on other available treatments and has failed these treatments or these are contraindicated; and
- 2 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- 3 Applicant has an up to date knowledge of the treatment options for acne and is aware of the safety issues around isotretinoin and is competent to prescribe isotretinoin; and
- 4 Patient has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and the applicant has ensured that, for female patients, the possibility of pregnancy has been excluded prior to the commencement of the treatment and that (where applicable) the patient is informed that she must not become pregnant during treatment and for a period of one month after the completion of the treatment.

#### Note

Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

## **Implementation, Education and Training**

From the beginning of January 2009, Special Authority forms will be made available on our website (under the Special Authorities section). Dermatologists should use these forms in advance of the 1 March 2009 implementation date for any new prescriptions that involve repeats in order to enable patients to continue to collect funded acitretin and isotretinoin after 1 March 2009. Unfortunately electronic Special Authorities will not be available until 1 March 2009.

The Royal New Zealand College of General Practitioners will continue to develop education, assessment and continuing professional development programmes that are relevant to the use of pharmaceuticals, including acitretin and isotretinoin. This will include the accreditation of appropriate learning modules and decision support tools for general practitioners.

We also understand that the Royal New Zealand College of General Practitioners will be developing communications to general practitioners to ensure that they are aware of the implications of the changes to the restrictions.

PHARMAC will be organising training opportunities in 2009 through PHARMAC's Seminar Series and information developed by bpac<sup>nz</sup>.

## Feedback Received regarding the Proposal

We appreciate all the feedback that we received and acknowledge the time that people took to respond. All consultation responses received were considered in making a decision on the proposed changes. A number of issues were raised in response to the proposal. The following table summaries the main themes and also PHARMAC's response to these concerns:

Theme	Response
<p>There was concern that there would be a lack of expertise by non-dermatologist prescribers in the management of acitretin and isotretinoin side effects if the restrictions were removed.</p>	<p>As funding for acitretin and isotretinoin is currently unavailable to non-dermatologist prescribers (although prescribing these pharmaceuticals has not been restricted to them), it can be expected that they will have little to no experience in the use of those pharmaceuticals. As such, some form of training should occur and this is emphasised in the Special Authorities requirement that the applicant has expertise in these pharmaceuticals. We note that the Royal New Zealand College of General Practitioners will be accrediting and promoting relevant training programmes.</p>
<p>There was concern that removing the prescriber restrictions would increase the numbers of pregnancies exposed to the risk of exposure to retinoids (predominantly in relation to isotretinoin).</p>	<p>While we acknowledge that these pharmaceuticals are teratogenic; it follows that if more people have access to retinoids that there may be an absolute (but not necessarily relative) increase in the number of pregnancies exposed to retinoids. As with any pharmaceutical the risk and benefit to an individual is something that would be weighed up by the prescriber and patient.</p> <p>Whether there would be an increase in the <i>proportion</i> of patients taking retinoids and becoming pregnant is not known. However given that different groups of patients would now have improved access it is possible that such changes might occur. There is data which shows that there is a relative increase in terminations of pregnancies amongst women in deprivation quintile five.</p> <p>We believe that close and ongoing contact with their general practitioner is the best way to reduce the risk of accidental pregnancy, especially if the general practitioner also provides contraception advice. In addition, the Special Authority requirements will ensure that patients are aware of the risks associated with becoming pregnant while on these pharmaceuticals.</p>
<p>There was concern raised that removing the prescriber restriction for isotretinoin would increase the risk of suicidal ideation.</p>	<p>Despite the debate as to whether there is evidence that this is a real side effect, we consider that a general practitioner is well placed to know a patient's medical history, and better positioned to detect symptoms of mental ill-health including depression and suicidal thoughts.</p>
<p>There was concern that there would be inappropriate pressure to prescribe isotretinoin and that if a general practitioner refuses to prescribe isotretinoin that the patient may go to another practice.</p>	<p>There was a concern that general practitioners would be pressured to prescribe isotretinoin in a time constrained consultation. We consider that this pressure is equally present, and may be more so, in the context of a private dermatology appointment. The matter of time constraint is one that needs to be addressed by the professional body and not PHARMAC.</p> <p>We note that the primary health care strategy contains inherent drivers to encourage continuity of care and therefore prevent patients switching prescribers. Casual patient attendances attract higher fees for doctor visits and prescription charges. We also note that a patient could currently choose to see another dermatologist if their current dermatologist will not prescribe a product for them.</p>

Theme	Response
	We also note that we are reviewing the funding of topical anti-acne treatments and the funding of the oral agent minocycline. A request for information has recently closed and we are working through issues arising from that process.
There was concern that widened access may result in an increased rate of reported adverse effects which may result in the withdrawal of the pharmaceuticals from the New Zealand market.	If there are additional safety concerns associated with wider access then they should be addressed in this case through way of regulation by Medsafe and not by funding restrictions.
There was some concern about the bureaucracy associated with putting these pharmaceuticals on a Special Authority.	Special Authority will ensure that all prescribers are reminded of the responsibilities associated with prescribing retinoids.  Special Authority also allows for closer control and audit of prescribing activity.

### Changes made as a result of consultation

As a result of feedback received during consultation we have applied a Special Authority to acitretin, which is similar to isotretinoin. The Special Authority addresses a number of the safety concerns raised.

There were some concerns regarding the use of credentialing. We have therefore removed this wording from the Special Authorities and instead we have used the regulatory classification “vocationally registered general practitioner” in the Health Practitioners Competency Assurance Act as suggested by the Royal New Zealand College of General Practitioners. We agree with the College’s view that it is inappropriate for a general practitioner to be “credentialed” to provide medical care which is within their scope of general practice.

We have also reduced the Special Authority for isotretinoin from being valid for 2 years to 1 year as this was considered to be a more adequate time period.