NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

7 March 2014

Decision to award sole supply to Tacrolimus Sandoz

PHARMAC has decided to award Tacrolimus Sandoz capsules Sole Subsidised Supply status in the community, and Hospital Supply Status in DHB hospitals. This was the subject of a consultation letter dated 30 January 2014. The consultation letter can be found at

- http://www.pharmac.health.nz/news/consultation-2014-01-30-tacrolimus/

Summary of the decision

The decision means that:

- Tacrolimus Sandoz will be listed on the Pharmaceutical Schedule from 1 May 2014;
- The Prograf brand of tacrolimus will continue to be listed until 1 November 2014, when Tacrolimus Sandoz will become the only brand of tacrolimus capsules listed until at least 31 October 2018;
- PHARMAC will continue to fully fund Prograf for intestinal transplant patients; and
- All existing patients (other than intestinal transplant patients) will need to change from Prograf to Tacrolimus Sandoz to continue to receive fully funded tacrolimus.

PHARMAC previously consulted on the proposal in December 2012. A revised proposal was developed following consideration of issues raised in this initial consultation and a second consultation letter issued on 30 January 2014. Refer to the link above for more detail and background information.

Several changes were made following consideration of consultation feedback received, including:

- A brand switch fee for pharmacists will apply to dispensing of Tacrolimus Sandoz; and
- The Wastage rule will be applied to dispensing of the Prograf brand of tacrolimus.

Details of the decision

From 1 May 2014, Sandoz's brand of tacrolimus capsules 0.5 mg, 1 mg and 5 mg (Tacrolimus Sandoz) will be listed in Section B, and Part II of Section H, of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer and excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Tacrolimus	Cap 0.5 mg	Tacrolimus Sandoz	100	$85.60
Tacrolimus	Cap 1 mg	Tacrolimus Sandoz	100	$171.20
Tacrolimus	Cap 5 mg	Tacrolimus Sandoz	50	$428.00

- From 1 November 2014, the Prograf (Janssen Ltd) brand of tacrolimus capsules 0.5 mg, 1 mg and 5 mg will be delisted from Section B, and Part II of Section H, of the Pharmaceutical Schedule.

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- Tacrolimus Sandoz will be the Sole Subsidised brand of tacrolimus capsules in the community and the Hospital Supply Status brand in DHB hospitals, with a DV Limit of 1% from 1 November 2014 to 31 October 2018.

- Tacrolimus Sandoz will be listed subject to the current Special Authority criteria and HML restriction for tacrolimus capsules, which limit funding to patients who are organ transplant recipients.

- Patients who currently receive funded Prograf approved via the EC/NPPA mechanism for non-transplant indications also need to change to Tacrolimus Sandoz to continue to receive fully funded tacrolimus. Existing approvals will be replaced with Tacrolimus Sandoz approvals at a time during the transition period agreed with the relevant clinician.

- Prograf will continue to be funded for the small number of existing intestinal transplant patients via the NPPA mechanism.

- A Brand Switch Fee will be applied on dispensing of Tacrolimus Sandoz from 1 November 2014 until 1 February 2015.

- The Wastage rule will be applied to dispensing of Prograf between 1 August 2014 and 31 October 2014 (a maximum of 90% of a pack).

Transition timelines

- 1 May 2014 –Tacrolimus Sandoz will be listed at the prices and subsidies specified above. There will be no change to the prices of and subsidies for Prograf.

- 1 May 2014 – 31 October 2014 – both the Tacrolimus Sandoz and Prograf brands will be fully funded.

    - Current intestinal transplant patients will automatically be issued with an EXCP number for continuation of funded Prograf via the NPPA mechanism.

    - A six-month transition period provides sufficient time for patients (other than intestinal transplant patients) who have been receiving funded Prograf to be transitioned to Tacrolimus Sandoz.

    - Tacrolimus Sandoz is bioequivalent to Prograf, however changing brands will require careful monitoring (see the **Managing the change** section below for more information).

    - During the transition period we recommend that **doctors prescribe by brand**, and that **pharmacists check with prescribers where a prescription is not by brand**, to avoid inadvertent, unmonitored, brand switches occurring at the pharmacy level.

- 1 August 2014 and 31 October 2014 – the Wastage rule will be applied to Prograf (maximum of 90% of a pack).

- 1 November 2014 –Prograf will be delisted from the Pharmaceutical Schedule.

- 1 November 2014 until 1 February 2015 - a Brand Switch Fee will be applied to Tacrolimus Sandoz.

- 1 November 2014 – 31 October 2018 – Tacrolimus Sandoz will be the only funded brand of tacrolimus in both the community and DHB hospitals.

Managing the change

PHARMAC has given very careful consideration and followed careful processes when making the decision to change the funded brand from Prograf to Tacrolimus Sandoz. While the two products are bioequivalent, tacrolimus is a narrow therapeutic index medicine, so clinical advice and international experience supports the need for careful therapeutic drug level monitoring for patients to change tacrolimus brands.

The exact tests, procedures and visits to be undertaken in order to change brands safely may be different for different transplant populations and individual patients. Brand changing will be managed by each patient's own transplant service to ensure the change is safe and carefully monitored throughout the transition. Patients will be contacted directly by their transplant service to explain how the brand change will be managed for them.

Patients who currently receive funded Prograf approved via the EC/NPPA mechanism for non-transplant indications will also need to change brands to Tacrolimus Sandoz in order to continue to receive fully funded tacrolimus. PHARMAC will be contacting clinicians and pharmacists involved in the care of these patients to explain the process and timelines for changing these patients.

PHARMAC will work closely with transplant services managing the brand change; providing general brand change guidelines and information for clinicians, pharmacists and patients which can be utilised and modified by each transplant service as it considers appropriate. Resources will also be developed to support pharmacies and primary and secondary care services. We will have these resources available and distributed as soon as possible.

Reminders in prescribing and dispensing software will be used, where possible, to assist with managing the brand change.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 14 February 2014 were considered in their entirety in making a decision on the proposed changes. Issues raised in the initial consultation in December 2012 were discussed in the consultation letter issued on 30 January 2014. Refer to link above for more detail.

The table below and on the following pages summarises the issues raised during the second consultation period in relation to specific aspects of the proposal:

Theme	PHARMAC Comment
Concern from transplant patients regarding switching to a generic for a critical medicine such as tacrolimus.	Noted. While PHARMAC considers that the brand change can be managed safely, we acknowledge that patients depend on this medicine and will be concerned about the change. Each patient will be carefully managed and monitored by their transplant service, usually a transplant co-ordinator or clinician. PHARMAC considers this is the most appropriate way of transitioning patients to Tacrolimus Sandoz. Patients will be contacted directly by their transplant service and will have the opportunity to discuss the brand change and receive the information they need.

Theme	PHARMAC Comment
Ability to prepare Tacrolimus Sandoz into an oral suspension for patients unable to swallow capsules who are not able to be managed with opening capsules is important (primarily used in paediatrics). Compounding of tacrolimus requires protective equipment and is not possible in every pharmacy. Although stability information is now available, there are concerns regarding the variability and consistency of tacrolimus suspension made by different pharmacies.	Stability information is now available for the preparation of tacrolimus 1 mg per ml oral suspension using Tacrolimus Sandoz capsules. As with Prograf, results from this testing indicate that a 30 day shelf life would be appropriate. The New Zealand standardised formulation batch sheet for tacrolimus will be updated by the Compounding Pharmacists Working Group to include Tacrolimus Sandoz and will be available from www.pharminfotech.co.nz. PHARMAC acknowledges the concerns expressed about needing protective equipment for compounding which are not available in every pharmacy, and concerns regarding variability and consistency, but notes that this is not an issue caused by the brand which is funded. These concerns currently exist for Prograf. However PHARMAC will work with paediatric transplant services and pharmacists to determine what resources could alleviate this issue. PHARMAC notes that oral liquid compounding is an off-label use for both Prograf and Tacrolimus Sandoz.
Is it possible to open the capsules and mix with water for administration to patients unable to swallow capsules?	It is possible to open Tacrolimus Sandoz capsules and mix with water for whole doses (0.5 mg increments) as is the current practice for some patients who are unable to swallow whole Prograf capsules. As tacrolimus is an immunosuppressant, precautionary measures are required to prevent unnecessary exposure to the person administering the medicine. PHARMAC notes opening capsules and mixing the contents with water is an off-label use for both Prograf and Tacrolimus Sandoz.
Support for the ability to obtain funded Prograf for patients that have genuine clinical difficultly with Tacrolimus Sandoz.	As with all medicines, PHARMAC is able to consider funding in exceptional circumstances via the NPPA Mechanism. PHARMAC is willing to assess NPPA applications for the funding of the Prograf brand of tacrolimus.
Support for the need of brand change guidelines and a careful monitoring process to be in place for the brand change to occur safely.	PHARMAC will work closely with transplant services to develop and produce the resources required to safely manage the brand change. Guidelines and resources developed by PHARMAC will be developed and be available for use by transplant and primary care sectors. PHARMAC will also support transplant services to develop their own detailed guidelines.

Theme	PHARMAC Comment
A double Brand Switch Fee should be applied to reflect the work undertaken by pharmacy.	The bulk of the brand change activity will be undertaken by transplant services. However, a single Brand Switch Fee has been applied during the first three months of Sole Supply to recognise the level of input expected from pharmacies to help manage the change and the other support that will be provided by transplant services and PHARMAC.
Drug disposal should be funded for patients who return unused Prograf supplies to community pharmacies.	The 30 January 2014 consultation letter stated advice on returning unused Prograf supplies would be incorporated in change guidelines to avoid inadvertent changing. PHARMAC will request transplant services accommodate the use of existing Prograf supplies in their transition plans, where possible, to reduce wastage. PHARMAC notes that this will not be possible for some patients, in which case patients should be asked to return unused Prograf supplies at the time of hospital clinic appointments. Therefore, the costs of disposal are likely to be managed by hospitals rather than community pharmacies.
Tacrolimus Sandoz and Prograf should have original pack (OP) or wastage rules applied to ensure the community pharmacies are protected from any potential financial loss due to part packs. Pharmacies should be able to claim for undispensed Prograf that remains at the end of the six month transition period.	PHARMAC notes the issues regarding possible costs incurred by community pharmacies as a result of the brand switch. While PHARMAC considers that pharmacies have sufficient time to manage their stock levels appropriately, as a precautionary measure the Wastage rule has been applied to Prograf for the last 3 months of the transition period. This will enable Pharmacies to claim for part packs of Prograf (90% of each strength).
Direct communication with pharmacies that manage the small number of intestinal transplant patients is required to ensure necessary processes in place to maintain supply of Prograf for these patients.	Noted. PHARMAC will communicate directly with the clinicians and pharmacies involved to support this process.
Support for the proposal. The savings made will enable other medicines to be funded.	Noted. Savings are important because they can be used to fund other medicines or healthcare. By making this change, PHARMAC is able to release funding to reinvest in medicines, creating opportunities for greater health gain all round.

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.