NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

7 August 2012

Decision to award sole supply for, and widen funded access to filgrastim

PHARMAC is pleased to announce the approval of an agreement with Sandoz BioPharmaceuticals, a Novartis company. This was the subject of a consultation letter dated 19 June 2012. In summary, the effect of the decision is that:

- Sandoz BioPharmaceuticals' brand of filgrastim 300 µg and 480 µg prefilled syringes (Zarzio) will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 September 2012;
- Zarzio will be funded, subject to Special Authority criteria, for cancer patients at risk of neutropenia, patients and donors undergoing stem cell transplantation procedures and patients with neutropenia due to non-cancer indications;
- Sole Subsidised Supply Status will be awarded to Zarzio (to be the only funded brand of filgrastim in the community) from 1 September 2012 until 31 December 2015; and
- Hospital Supply Status will be awarded to Zarzio (the only available brand in DHB hospitals subject to a 1% discretionary variance limit) from 1 January 2013 until 31 December 2015.

Details of the proposal

- From 1 September 2012, filgrastim 300 µg and 480 µg prefilled syringes (Zarzio) will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following subsidies and prices (ex-manufacturer and excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Filgrastim	Inj 300 µg per 0.5ml prefilled syringe	Zarzio	5	$540.00
Filgrastim	Inj 480 µg per 0.5ml prefilled syringe	Zarzio	5	$864.00

- Zarzio will be subject to confidential rebates, which will reduce its net price to the Funder.
- Filgrastim will be listed in Section B of the Pharmaceutical Schedule subject to the following Special Authority criteria:

> **Special Authority for Subsidy**
> **Initial application** from any relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
> Any of the following:

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1. Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer febrile neutropenia risk ≥ 20%*); or
2. Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation; or
3. Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation; or
4. Treatment of severe chronic neutropenia (ANC < 0.5 x 10^9/L); or
5. Treatment of drug-induced prolonged neutropenia (ANC < 0.5 x 10^9/L).

Note *Febrile neutropenia risk ≥ 20% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

- We note that these criteria differ from those consulted upon - only a relevant specialist or vocationally registered general practitioner can apply for Special Authorities, not any medical practitioner.

- The current restrictions applying to filgrastim recorded in Part III of Section H (Discretionary Community Supply) will be amended from 1 September 2012, as follows (additions in bold, deletions in strikethrough):

Inj 300µg per 0.5ml prefilled syringe	Neupogen **Zarzio**
Inj 300µg per 1ml vial	Neupogen
Inj 480µg per 0.5ml prefilled syringe	Neupogen **Zarzio**

Indefinite supply for **any of the following indications** ~~any appropriate indication for the management of patients with cancer~~**:**

Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer febrile neutropenia risk ≥ 20%*)
Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation
Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation
Treatment of severe chronic neutropenia (ANC < 0.5 x 10^9/L)
Treatment of drug-induced prolonged neutropenia (ANC < 0.5 x 10^9/L)

- Zarzio will be awarded community Sole Subsidised Supply Status for the 300 µg and 480 µg filgrastim prefilled syringes from 1 September 2012 until 31 December 2015.

- Zarzio will be awarded Hospital Supply Status for the 300 µg and 480 µg filgrastim prefilled syringes from 1 January 2013 until 31 December 2015 with a 1% Discretionary Variance (DV) limit.

- The Neupogen (Roche) brand of filgrastim 300 µg and 480 µg prefilled syringes, currently listed in Parts II and III of Section H of the Pharmaceutical Schedule, will be delisted from 1 January 2013.

- The filgrastim 300 µg vial (Neupogen, Roche) and pegfilgrastim 6 mg prefilled syringe (Neulastim, Roche) will remain listed in Section H (Parts II and III).

- Sandoz BioPharmaceuticals' brand of filgrastim 300 µg vial (Zarzio) is currently in development and will be listed in Section B and Parts II and III of Section H of the Pharmaceutical Schedule once it is registered in New Zealand.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 10 July 2012 were considered in their entirety in making a decision on the proposed changes. All responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Filgrastim use in healthy stem cell donors Some clinicians raised the issue of maintaining the use of Neupogen in this group of patients due to potential risk of mutagenicity and immunogenicity with a biosimilar filgrastim, a risk which is probably unacceptable in healthy stem cell donors. This would be in line with international guidelines.	The Cancer Treatments Subcommittee of PTAC discussed this issue at its November 2011 meeting and considered that there is currently no evidence that biosimilar filgrastim has a different safety profile in healthy donors when compared to patient groups requiring treatment for various indications. The Subcommittee considered that whilst at this time such a risk remained theoretical, hospitals should be allowed to purchase an alternative brand of filgrastim for healthy stem cell donors if they choose to. These minutes can be accessed at: http://www.pharmac.govt.nz/2012/04/20/2011 This decision to award Hospital Supply Status to Zarzio allows hospitals to use an alternative brand of filgrastim for a limited number of patients including healthy stem cell donors which would fall within the 1% Discretionary Variance (DV) limit.
Filgrastim dispensing We received some feedback that filgrastim should be subject to Original Pack (OP) dispensing where pharmacies can claim for full packs of filgrastim to avoid them being left with opened packs with unused prefilled syringes.	We have considered this request but will be unable to implement it due to the significant cost associated with it and the wastage that would occur. Zarzio has a 30 month shelf-life which should help pharmacies use up opened packs. The majority of patients will also require multiple prefilled syringes to be dispensed, therefore we consider it unlikely that pharmacies would be unable to sell through opened packs.
Funding of pegfilgrastim Some respondents also requested that PHARMAC consider listing pegfilgrastim in Section B of the Pharmaceutical Schedule. They noted it involves fewer injections compared with filgrastim, requires less blood monitoring and possibly less outpatient nursing support.	This decision does not prevent hospitals from funding pegfilgrastim for patients as is the case currently. We are willing to consider a funding application for pegfilgrastim on Section B of the Pharmaceutical Schedule.

More information

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