

16 May 2014

Decision to award somatropin sole supply to Novartis New Zealand Limited

PHARMAC is pleased to announce the approval of the proposal to award Sole Subsidised Supply Status in the community, and Hospital Supply Status in DHB hospitals, to Novartis' brand of somatropin, Omnitrope. Omnitrope is supplied by Sandoz – a Novartis New Zealand Ltd company. This was the subject of a consultation letter dated 21 March 2014. The consultation letter can be found at

<http://www.pharmac.health.nz/news/consultation-2014-03-21-somatropin/>.

Summary of the decision

The decision means that:

- Omnitrope will be listed in Section B (community) and Part II of Section H (hospital) of the Pharmaceutical Schedule subject to Special Authority restrictions from July 2014;
- The Genotropin brand of somatropin will continue to be listed until 31 December 2014. Omnitrope will become the only subsidised brand of somatropin injections subsidised from 1 January 2015 until 31 December 2017;
- All existing patients will need to change from Genotropin to Omnitrope to continue to receive fully funded somatropin;
- The Paediatric and Adult Growth Hormone Panels will be disestablished.
- Endocrinologists and Paediatric Endocrinologists will be able to apply for Special Authority approval for funded somatropin and patient's treating physicians will be able to write prescriptions for funded somatropin for any of their patients who have a Special Authority approval;
- The current direct distribution model of growth hormone will change. Patients will present their prescription for funded somatropin to a community pharmacy and will be dispensed Omnitrope.

Several changes were made following consideration of consultation feedback:

- Patient co-payments will be waived for Omnitrope from 1 July 2014 to 31 December 2014;
- A Brand Switch Fee will apply to dispensing of Omnitrope from 1 January 2015 to 31 March 2015; and
- The proposed Special Authority was amended to restrict applications to those made by Endocrinologists and Paediatric Endocrinologists.

Details of the decision

- From 1 July 2014 Sandoz's brand of somatropin injections 5 mg, 10 mg and 15 mg will be listed in Section B (community), and Part II of Section H (DHB hospital), of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer and excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Somatropin	Inj 5 mg cartridge	Omnitrope	1	\$109.50
Somatropin	Inj 10 mg cartridge	Omnitrope	1	\$219.00
Somatropin	Inj 15 mg cartridge	Omnitrope	1	\$328.50

- Omnitrope will be the Sole Subsidised Supply brand of somatropin in the community and Hospital Sole Supply brand in DHB hospitals with a DV limit of 1% from 1 January 2015 to 31 December 2017.
- From 1 January 2015 the Genotropin (Pfizer Ltd) brand of somatropin injections 16 iu (5.3 mg) and 36 iu (12 mg) will be delisted from Section B and Part II of Section H, of the Pharmaceutical Schedule.
- Omnitrope will be listed subject to Special Authority criteria and an HML restriction substantially the same as that set out in the consultation letter, excepting that it restricts applications to those made by Endocrinologists including Paediatric Endocrinologists.
- Paediatric patients who currently receive funded Genotropin, via an approval from the New Zealand Growth Hormone Committee, will continue to receive funded growth hormone. Paediatric patients who have been newly approved to receive funded growth hormone will receive Omnitrope at a time during the transition period agreed with the relevant clinician responsible for the Special Authority application and prescription of the approved Omnitrope.
- Adult patients who currently receive funded Genotropin, via an approval from the Adult Growth Hormone Panel, will continue to receive funded growth hormone. Adult patients who have been newly approved to receive funded growth hormone will receive Omnitrope at a time during the transition period agreed with the relevant clinician responsible for the Special Authority application and ongoing prescribing of the approved Omnitrope.
- Every patient who currently receives funded Genotropin (whether adult or paediatric) will be visited by an educator from Novartis during the transition period (1 July 2014 - 31 December 2014) who will teach them how to use the Omnitrope auto-injector. Novartis will be in direct contact with patient's to arrange this visit."
- Patient prescription co-payments, charged by pharmacies when patients collect their medicine, will be waived for Omnitrope dispensings from 1 July to 31 December 2014.
- A Brand Switch Fee for pharmacists will apply to dispensing of Omnitrope from 1 January 2015 until 31 March 2015.

Transition Timelines

- 1 July 2014 Omnitrope will be listed at the prices and subsidies specified above. There will be no change to the prices for Genotropin.
- 1 July 2014 -31 December 2014 both the Omnitrope and the Genotropin brands will be fully funded.
 - Existing patients on somatropin will have a Special Authority approval number automatically generated for application renewals valid for 12 months of growth hormone.
 - Patients who have been receiving funded Genotropin will be transitioned to Omnitrope.
- Patient prescription co-payments will be waived for Omnitrope dispensed by community pharmacy from 1 July 2014 to 31 December 2014.
- 1 January 2015 – Genotropin will be delisted from the Pharmaceutical Schedule
- 1 January 2015 until 31 March 2015 – a Brand Switch Fee for pharmacists will be applied to Omnitrope.
- 1 January 2015 to 31 December 2017 Omnitrope will be the only funded brand of somatropin in both the community and in DHB hospitals.

Managing the change

PHARMAC has given very careful consideration and sought expert clinical advice when making the decision to change the funded brand from Genotropin to Omnitrope. Omnitrope injection has been approved by Medsafe on the basis of bioequivalence to Genotropin injections. They both contain the same amount of the active ingredient somatropin.

PHARMAC will be communicating directly with patients, clinicians and pharmacists affected by this decision to ensure that they understand all of the changes and what actions each group needs to take in order to ensure patients continue to receive their fully funded somatropin in a timely manner.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 4 April 2014 were considered in their entirety in making a decision on the proposed changes.

A summary of the key issues and questions raised, and PHARMAC comments on these issues, are discussed in the table on the following pages:

Theme	Comment
I have no objection to changing supplier of growth hormone if it frees up funds for other medicines.	Noted
I can accept these changes are for the good –	Noted. This decision ensures that a fully

my main concern is that this drug will still be funded by the government	funded somatropin will be maintained.
I do not have a concern with PHARMAC changing growth hormone brands, as long as the pharmacological action of Omnitrope is identical to Genotropin	Noted
NZ has a deskilled workforce with regard to growth hormone prescribing. Therefore prescribing of growth hormone should fall to Endocrinologists or specialists with an interest in Endocrinology	<p>PHARMAC has decided to restrict authority to apply for and seek renewal of funding for growth hormone via the Special Authority to Endocrinologists and Paediatric Endocrinologists.</p> <p>PHARMAC is not able to restrict who can prescribe a medicine, its role is solely to determine how and to which patients funding will be allocated. We acknowledge that the funding approval and prescribing /distribution mechanism that PHARMAC has managed for many years has had an impact; so we are planning some educational and {xxx] activities over the next 6 – 12 months to support pediatricians or other prescribers.</p>
No concerns around brand change but concerned at the disestablishment of the panels. Panels provided an impartial expert review of applications with excellent follow-up and feedback.	<p>The New Zealand Growth Hormone Committee (NZGHC) was established to ensure consistency of interpretation and to manage approvals of growth hormone funding within a budgetary cap. However now, with the cost of the drug significantly reduced, it is not necessary to manage the cost in this way. PHARMAC is comfortable that the Special Authority criteria will ensure that funding is targeted to those who would receive the best health outcomes.</p> <p>PHARMAC recognises the invaluable professional input and contribution both NZGHC and the Adult Panel have made to managing the funding for and treating patients with growth hormone.</p> <p>PHARMAC is in discussion with members of the NZGHC regarding potential advisory and educational services during the transition period and beyond.</p>
Will Omnitrope work the same as Genotropin?	Omnitrope injection has been approved by Medsafe on the basis of bioequivalence to Genotropin injections. They both contain the same amount of the active drug somatropin. Equally, both Omnitrope and

	Genotropin proved to have comparable bioavailability, safety and efficacy profiles.
How will the extra costs to patients be managed and will there be transition education for patients?	<p>Patients will have their prescription co-payments waived during the 6 month transition period from 1 July 2014 to 31 December 2014.</p> <p>A comprehensive educational programme implemented by trained educators will be provided by Sandoz to patients during the transition period. Every patient will receive a visit to learn how to use the Omnitrope product, before they are required to change to it. PHARMAC will ensure patients are well informed with clear information documents prior to the changes occurring.</p>
Concerned about the lack of forward planning in the consultation about how patients will dispose of their full sharps containers.	Sandoz will provide sharps containers as is the current practice with Genotropin. Disposal of the full sharps containers is not a problem specific to growth hormone and may require cooperation between organisations. For some patients it is possible to take the full container to pharmacies or back to their clinics at the time of appointments. PHARMAC staff are aware that some DHBs have, or are looking at waste disposal services through community pharmacy.
Asked if endocrine/paediatric nurse practitioners will be able to prescribe.	Nurse Practitioners will not be able to apply for special authority funding approval. As noted above, PHARMAC is not able to restrict who can prescribe a medicine, its role is solely to determine how and to which patients funding will be allocated.
Will Omnitrope cause my child to grow more rapidly than Genotropin, and therefore exacerbate his issues?	The two brands have been shown to have bioequivalence and bioavailability in the comparator studies so there should be no difference in the growth rate of patients.
Having to learn how to use a new pen is bothersome. The old one is familiar.	<p>We appreciate that any change can often be challenging and requires learning something new. The new pen is very similar to the current pen and we expect it to be just as easy to use once patients are familiar with it.</p> <p>Every patient will be visited by a product specialist who will teach them how to use the new pen. There will also be written</p>

