

30 June 2010

Lantus (insulin glargine), Apidra (insulin glulisine), Proctosedyl (hydrocortisone with cinchocaine) and Betadine (povidone iodine) funding proposal approved

PHARMAC is pleased to announce the approval of an agreement with Sanofi Aventis Limited for the listing and supply of insulin glargine (Lantus), insulin glulisine (Apidra), hydrocortisone with cinchocaine (Proctosedyl) and povidone iodine (Betadine).

In summary, the effect of the decision is that:

- Initially, access to insulin glargine (Lantus) will be widened by removing the current Special Authority criteria and replaced with a prescriber note targeting access for certain type 1 and type 2 diabetes patients.
- After 18 months, provided there are no changes to the data sheet, access to insulin glargine (Lantus) will be widened by removing the prescriber note in its entirety.
- Insulin glulisine (Apidra) will be funded without any access criteria.
- Hydrocortisone with cinchocaine (Proctosedyl) will be funded.
- The terms of listing of povidone iodine (Betadine) will be amended.

This was the subject of a consultation letter dated 24 May 2010.

Details of the decision

Insulin Glargine (Lantus)

- Lantus will remain listed in Section B and Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST) from 1 August 2010:

Pharmaceutical	Brand	Form and Strength	Pack Size	Price and subsidy
Insulin glargine	Lantus	Injection 100 IU/ml	1 x 10 ml vial	\$63.00
Insulin glargine	Lantus	Injection 100 IU/ml	5 x 3 ml cartridge	\$94.50
Insulin glargine	Lantus	Injection 100	5 x 3 ml pre-	\$94.50

	SoloStar	IU/ml	filled cartridge	
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- The current Special Authority that applies to Lantus will be removed from 1 August 2010 and replaced with the following prescriber note:

Note: Only for patients meeting one of the following criteria:

- Type 1 diabetes; or
 - Other condition related diabetes (e.g. Cystic Fibrosis, diabetes in pregnancy, pancreatectomy patients); or
 - Type 2 diabetes after there has been unacceptable hypoglycaemic events with a 3 month trial of an insulin regimen; or
 - Type 2 diabetes who require insulin therapy and who require assistance from a carer or healthcare professional to administer their insulin injections.
- The above prescriber note will be removed from 1 February 2012 subject to no changes, limiting the indications or increasing the warnings, precautions or contraindications, being made to the Lantus datasheet prior to this date.
 - A confidential rebate will apply to Lantus, reducing the net subsidy paid for this medicine.
 - Lantus will have protection from subsidy reduction and delisting until 1 August 2015.

Insulin glulisine (Apidra)

- Apidra will be listed in Section B and Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST):

Pharmaceutical	Brand	Form and Strength	Pack Size	Price and subsidy	Listing date
Insulin glulisine	Apidra	Injection 100 IU/ml	1 x 10 ml vial	\$27.03	1 August 2010
Insulin glulisine	Apidra	Injection 100 IU/ml	5 x 3 ml cartridge	\$46.07	1 September 2010
Insulin glulisine	Apidra SoloStar	Injection 100 IU/ml	5 x 3 ml pre-filled cartridge	\$46.07	1 August 2010

- Apidra will be listed with no Special Authority or endorsement restrictions.
- Apidra will have protection from subsidy reduction and delisting until 1 August 2013.

Hydrocortisone with cinchocaine (Proctosedyl)

- Proctosedyl will be listed in Section B and Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST) from 1 August 2010:

Pharmaceutical	Brand	Form and Strength	Pack Size	Price and subsidy
Hydrocortisone with cinchocaine	Proctosedyl	Oint 5 mg and cinchocaine hydrochloride 5 mg per g	30 g	\$15.00
Hydrocortisone with cinchocaine	Proctosedyl	Suppos 5 mg, and cinchocaine hydrochloride 5 mg	12	\$9.90

- Confidential rebates will apply to Proctosedyl, reducing the net subsidy paid for this medicine.

Povidone iodine (Betadine)

- The listing for Betadine will be amended (where applicable) in Section B and Section H of the Pharmaceutical Schedule from 1 August 2010 as follows (prices ex-manufacturer, excluding GST) :

Pharmaceutical	Brand	Form and Strength	Pack Size	Price and subsidy
Povidone iodine	Betadine	Ointment 10%	25 g	\$3.27
Povidone iodine	Betadine	Antiseptic solution 10%	500 ml	\$6.20
Povidone iodine	Betadine	Alcohol skin preparation 10% with 30% alcohol	500 ml	\$10.00

What changes were made following consultation?

We initially proposed that the listing of Lantus in Section B of the Pharmaceutical Schedule would be subject to subsidy by endorsement restrictions. After consideration of the issues involved in implementing this proposal, including the potential associated compliance costs, we decided instead to use a prescribing note alongside the listing; however the note maintains the restriction on subsidies to the same patient population as the proposed endorsement. On balance, we considered that the prescriber note provides the same clinical guidance and intent in relation to access to subsidies as recommended by the Diabetes Subcommittee.

What feedback was received?

We appreciate the feedback we received and acknowledge the time people took to respond to our consultation. All consultation responses received by 11 June 2010 were considered in the decision on the proposed changes.

Most responses were supportive of the proposals. The following common themes were raised in relation to specific aspects of the proposal:

Theme Raised During Consultation	PHARMAC Comment
Some responders suggested that diabetes in pregnancy and pancreatectomy patients should be included in the access criteria.	We had intended that these groups would be included as part of the "other related conditions" criteria; so we have specifically named these groups in the prescribing note for the avoidance of doubt.
Funding should be provided to the alternative long-acting insulin (insulin detemir).	Our agreement with Sanofi Aventis is not a sole supply agreement. We remain open to funding insulin detemir (either as a first line or second line treatment) subject to reaching an acceptable agreement with the supplier.
The registered indications for Apidra are different to the alternative funded rapid acting insulin NovoRapid.	We note that there are some differences in the registered indications and recommend that prescribers refer to the datasheets.

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.