

8 August 2012

Proposal relating to sole supply of blood glucose meters and test strips approved

The PHARMAC Board has approved a proposal to list CareSens blood glucose meters and test strips through an agreement with Pharmaco (NZ) Ltd. The proposal to widen access to blood glucose meters and test strips to two small patient groups has also been approved. This was the subject of a consultation letter dated 23 February 2012.

In summary, the effect of the decision is that:

- CareSens N, CareSens II and CareSens N POP blood glucose meters will be funded from 1 September 2012, and CareSens will be the only brand of funded blood glucose meters from 1 December 2012;
- CareSens and CareSens N blood glucose test strips will be funded from 1 September 2012 and will be the only brand of funded test strips from 1 March 2013 with the following exceptions:
 - Patients testing both ketones and blood glucose with the Freestyle Optium meter prior to 1 June 2012 will be able to continue to access funded Freestyle Optium test strips beyond 1 March 2013;
 - Patients using the Accu-Chek Combo insulin pump, which has an integrated blood glucose meter, prior to 1 June 2012 will be able to continue to access funded Accu-Chek Performa test strips beyond 1 March 2013.
- Freestyle Optium blood glucose test meters will be deleted from the Blood Glucose Testing Subgroup and moved into the Ketone Testing Subgroup of Section B of the Pharmaceutical Schedule from 1 December 2012 (subject to restrictions);
- Pharmacists will be eligible to prescribe and claim one funded CareSens meter to eligible patients between 1 September 2012 until 1 March 2013;
- A Brand Switch Fee will apply to dispensing's of CareSens blood glucose meters between 1 September 2012 and 1 March 2013;
- Funding for a blood glucose meter and test strips will be available for patients on home Total Parenteral Nutrition (TPN) at risk of hypoglycaemia or hyperglycaemia and for patients with a genetic or acquired disorder of glucose homeostasis from 1 September 2012.

The funding of Sensocard test strips for the vision impaired will not be affected by this decision.

Details of the proposal

With regard to blood glucose meters

- The following blood glucose diagnostic test meters will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 September 2012 each at the price and subsidy set out below (ex-manufacturer, excl. GST):

Chemical	Presentation	Product	Pack Size	Subsidy & Price
Blood glucose diagnostic test meter	1 meter with: 50 lancets, a lancing device, and 10 diagnostic test strips	CareSens N	1 OP	\$20.00
Blood glucose diagnostic test meter	1 meter with: 50 lancets, a lancing device; and 10 diagnostic test strips	CareSens N POP	1 OP	\$20.00
Blood glucose diagnostic test meter	1 meter with: 50 lancets, a lancing device; and 10 diagnostic test strips	CareSens II	1 OP	\$20.00

- CareSens II and CareSens POP blood glucose diagnostic test meter (current listings) will be delisted from Section B and Part II of Section H of the Pharmaceutical Schedule from 1 October 2012;
- Sole Supply Status in the community (Section B of the Pharmaceutical Schedule), will apply to CareSens N, CareSens II and CareSens N POP blood glucose diagnostic test meters from 1 December 2012 until 30 June 2015;
- FreeStyle Lite, Accu-Chek Performa and On Call Advanced blood glucose diagnostic test meters will be delisted from Section B of the Pharmaceutical Schedule from 1 December 2012;
- The restrictions applying to blood glucose diagnostic meters will be amended from 1 September 2012 as follows (additions in bold, deletions in ~~strike-through~~):

BLOOD GLUCOSE DIAGNOSTIC TEST METER – Subsidy by endorsement

- a) Maximum of 1 meter per prescription
- b) A diagnostic blood glucose test meter is subsidised for a patient who:
 - i. **is receiving** ~~begin~~ insulin or sulphonylurea therapy ~~after 1 March 2005~~;
 - or
 - ii. ~~is prescribed for a pregnant woman~~ with diabetes; **or**
 - iii. **is on home TPN at risk of hypoglycaemia or hyperglycaemia; or**
 - iv. **has a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome.**

~~Only one meter per patient. No further prescriptions will be subsidised. The prescription must be endorsed accordingly.~~

Only one CareSens meter per patient. No further prescriptions will be subsidised for patients who already have a CareSens meter. For the avoidance of doubt patients who have previously received a funded meter, other than CareSens, are eligible for a CareSens meter.

The prescription must be endorsed accordingly.

Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylureas.

- The restrictions applying to blood glucose diagnostic meters will be amended from 1 March 2013 as follows (additions in bold, deletions in ~~strike through~~):

BLOOD GLUCOSE DIAGNOSTIC TEST METER – Subsidy by endorsement

- a) Maximum of 1 meter per prescription
- b) A diagnostic blood glucose test meter is subsidised for a patient who:
 - i. is receiving insulin or sulphonylurea therapy; or
 - ii. is pregnant with diabetes; or
 - iii. is on home TPN at risk of hypoglycaemia or hyperglycaemia; or
 - iv. has a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome.

Only one meter per patient. No further prescriptions will be subsidised. The prescription must be endorsed accordingly.

~~Only one CareSens meter per patient. No further prescriptions will be subsidised for patients who already have a CareSens meter. For the avoidance of doubt patients who have previously received a funded meter, other than CareSens, are eligible for a CareSens meter.~~

~~The prescription must be endorsed accordingly.~~

~~Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylureas.~~

- The listing for Freestyle Optium blood glucose test meter will be amended, by removing it from the Blood Glucose Testing Subgroup and moving it into the Ketone Testing Subgroup of the Alimentary and Metabolism Therapeutic Group, Section B of the Pharmaceutical Schedule as a ketone blood testing meter, from 1 December 2012, at a price and subsidy of \$9.00 per meter (ex-manufacturer, excl. GST) with the following restrictions:
 - a) Only on a prescription
 - b) Only one meter per patient, no further prescriptions will be subsidised.
- A brand switch fee of \$4.50, plus handling fee, for funded CareSens blood glucose meters will listed be in Section B of the Pharmaceutical Schedule and be available to Pharmacists from 1 September 2012 until 1 March 2013.

With regard to Blood Glucose Test Strips

- CareSens N and CareSens blood glucose diagnostic test strips will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 September 2012 at a price and subsidy of \$10.56 per 50 test strips OP (ex-manufacturer, excl. GST);

- The price and subsidy of CareSens blood glucose diagnostic test strips with 5 lancets will be amended in Section B and Part II of Section H of the Pharmaceutical Schedule on 1 September 2012 as follows (prices ex-manufacturer, excl. GST):

Chemical	Presentation	Product	Pack Size	Current Subsidy and price	New Subsidy and price
Blood glucose diagnostic test strips	50 test strips and 5 x lancets, 50 test OP	CareSens	50 test OP	\$19.60	\$10.56

- The criteria applying to blood glucose diagnostic test strips will be amended from 1 September 2012 as follows (additions in bold):

BLOOD GLUCOSE DIAGNOSTIC TEST STRIP

The number of test strips available on a prescription is restricted to 50 unless:

1. Prescribed with insulin or a sulphonylurea but are on a different prescription and the prescription is endorsed accordingly; or
 2. Prescribed on the same prescription as insulin or a sulphonylurea in which case the prescription is deemed to be endorsed; or
 3. Prescribed for a pregnant woman with diabetes and endorsed accordingly; **or**
 4. **Prescribed for a patient on home TPN at risk of hypoglycaemia or hyperglycaemia; or**
 5. **Prescribed for a patient with a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome.**
- Sole Supply Status, in the community (Section B of the Pharmaceutical Schedule) will apply to CareSens N blood glucose diagnostic test strips and CareSens blood glucose diagnostic test strips from 1 March 2013 until 30 June 2015;
 - On Call Advanced blood glucose diagnostic test strips and lancets and the FreeStyle Lite blood glucose diagnostic test strips will be delisted from Section B of the Pharmaceutical Schedule from 1 March 2013;
 - The SensoCard brand of blood glucose test strips will be moved to a new chemical entity entitled: Blood glucose test strips (visually impaired) from 1 September 2012 and the following restrictions will apply:

BLOOD GLUCOSE DIAGNOSTIC TEST STRIP (Visually Impaired)

The number of test strips available on a prescription is restricted to 50 unless:

1. Prescribed with insulin or a sulphonylurea but are on a different prescription and the prescription is endorsed accordingly; or
2. Prescribed on the same prescription as insulin or a sulphonylurea in which case the prescription is deemed to be endorsed; or
3. Prescribed for a pregnant woman with diabetes and endorsed accordingly; **or**
4. Prescribed for a patient on home TPN at risk of hypoglycaemia or hyperglycaemia; or
5. Prescribed for a patient with a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome.

SensoCard blood glucose test strips are subsidised only if prescribed for a patient who is severely visually impaired and is using a SensoCard Plus Talking Blood Glucose Monitor.

- Accu-Chek Performa and FreeStyle Optium blood glucose diagnostic test strips will remain listed in Section B of the Pharmaceutical Schedule, subject to Special Authority access criteria allowing funded access for patients who were dispensed the Freestyle Optium meter to test ketones and blood glucose and patients who were dispensed Accu-Chek Combo insulin pump prior to 1 June 2012;
- Details of Special Authority access criteria for Accu-Chek Performa and FreeStyle Optium blood glucose diagnostic test strips will be notified once an appropriate agreement has been reached with the suppliers and is conditional on consultation and Board (or Chief Executive under delegated authority) approval

With regard to Schedule Rules

To augment the implementation process, the Pharmaceutical Schedule rules will be amended from 1 September 2012 until 1 March 2013 to allow pharmacists to provide a funded CareSens blood glucose meter to patients during the transition period, where the pharmacist has a record of the patient using insulin or a sulphonylurea.

Pharmacist generated prescriptions for the CareSens meters will only be subsidised for the 6 month period from 1 September 2012 until 1 March 2013.

Implementation support activities

PHARMAC will work closely with the supplier, health professionals and consumer groups to make sure that the right information is provided to consumers so they are able to operate a new meter.

A range of activities are planned for implementation that include:

- Provision of education and training to health professionals and consumers in use of newly subsidised meters and test strips;
- A nationwide series of events that support health professionals and consumers in learning about the meters.
- Provision of mechanisms for patients to receive a funded meter without a visit to a general practitioner
- Swap-out meter facilities including the provision of e-waste disposal of returned meters.

Feedback received

We appreciate all the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 14 March 2012 were considered in their entirety in making a decision on the proposed changes. The main themes identified during the consultation process were:

- The technical differences between the available meters and the clinical implications of switching meters.
- The risks associated with sole supply.
- The resource implications of a meter swap out for 120,000 patients.

A full summary of the consultation feedback on the blood glucose meters and test strip proposal can be viewed at www.pharmac.govt.nz/diabetes

More information

Our website contains further information about the changes to diabetes product funding and includes a Q&A section, Board papers and consultation summary report. This can be viewed at www.pharmac.govt.nz/diabetes.

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.