Diabetes Management Products

16 November 2017

PHARMAC

Pharmaceutical Management Agency



What we're doing

We're pleased to announce the approval of a new sole supply arrangement with Pharmaco (NZ) Limited for an expanded range of CareSens self-monitoring diagnostic test meters and associated test strips from 1 February 2018 until 30 June 2022. The decision will result in:

- Widened access to a blood ketone meter (CareSens Dual), so that funded blood ketone testing products will be available for all people:
 - with Type 1 diabetes;
 - with permanent neonatal diabetes;
 - who have undergone a pancreatectomy;
 - with cystic fibrosis related diabetes; and
 - with metabolic disease or epilepsy under the care of a paediatrician, neurologist or metabolic specialist.
- From 1 August 2018 the following diabetes management products will not be funded:
 - the CareSens II meter and its associated test strips;
 - o the Freestyle Optium meter and its associated test strips; and
 - the Accu-Chek Performa blood glucose test strips.
- To keep using a funded meter and test strips, approximately 3,000 people will need to change from their current brand of meter, and approximately 15,000 people will need to upgrade their current CareSens meter.
- People that need to change will have a choice of four CareSens funded meters.
- There will be a six-month transition period from 1 February 2018 31 July 2018 for these people to change brands or upgrade to a newer CareSens meter. During this period:
 - Pharmacists will be able to initiate a change of meter for eligible people;
 - Patients will not need to pay any co-payment for a new meter; and
 - Pharmacies will be able to claim a Brand Switch Fee when they've supported a person to change funded meters.
- PHARMAC will be talking with diabetes healthcare professionals over the next few months to finalise the criteria and a process to allow some people, who have specific clinical circumstances, to maintain funded access to their existing meter and test strips. We intend to release further information regarding this process before April 2018.

More information about what this decision will mean for you is available on our <u>diabetes</u> <u>webpage</u>, which will be regularly updated.

We are grateful for all the consultation feedback we received about new and emerging diabetes technologies. For the avoidance of doubt, the sole supply agreement with Pharmaco would not prevent the funding of continuous blood glucose monitoring systems (CGMS) and other hybrid systems during its exclusivity term. PHARMAC is interested in new diabetes management technology and we are currently assessing funding applications for two different CGMS systems. We will assess such technology and devices for funding using our standard process, which includes seeking specialist clinical advice.



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Any changes to the original proposal?

This decision was subject to a <u>consultation letter</u> dated 25 July 2017, amended 4 August 2017, and having carefully considered consultation feedback, we have made the following changes:

- The CareSens and KetoSens brands will be listed in Section H (Hospital Medicines List) but Hospital Sole Supply will not be awarded.
- Prescriptions for dual blood glucose and blood ketone diagnostic test meters written by metabolic specialists will be funded.
- Patients will be able to change their meter by visiting their local pharmacy and patient co-payments will be waived on all four CareSens meters during the transition period.
- Pharmacists will be able to initiate a funded change of meter, should they wish to, for those people who need to change and who are entitled to a new funded meter.
- Pharmacies will be able to claim a Brand Switch Fee for dispensings of CareSens meters during the transition period.



Who we think will be most interested

- All people living with diabetes, their caregivers and consumer groups representing people living with diabetes who need to monitor blood glucose/blood ketones.
- All health care professionals who support people who need to monitor blood glucose/blood ketones.
- Suppliers and wholesalers.



Detail about this decision

The following changes will occur in Section B and Part III of Section H of the Pharmaceutical Schedule.

Section B changes

From 1 February 2018:

- The following new products will be listed:
 - CareSens N Premier blood glucose diagnostic test meter;
 - o CareSens PRO blood glucose diagnostic test strips; and
 - CareSens Dual blood glucose and blood ketone meter and KetoSens blood ketone test strips.

with restrictions, at the price and subsidies (ex-man., ex-GST) set out in the table below:

Pharmaceutical	Presentation	Brand	Pack size	Price & subsidy
Blood glucose diagnostic test meter	Meter with 50 lancets, a lancing device and 10 blood glucose diagnostic test strips	CareSens N CareSens N POP CareSens N Premier	1 OP 1 OP 1 OP	\$10.00 \$10.00 \$20.00

Blood glucose diagnostic test strip	Test strip	CareSens N CareSens PRO	50 test OP 50 test OP	\$10.56 \$10.56
Dual blood glucose and blood ketone diagnostic test meter	Meter with 50 lancets, a lancing device and 10 blood glucose diagnostic test strips	CareSens Dual	1 OP	\$20.00
Blood ketone diagnostic test strip	Test strip	KetoSens	10 strip OP	\$15.50

Please note – All the subsidies are subject to a confidential rebate. Further details on the CareSens meters can be found on <u>Pharmaco's webpage</u>.

• Funding restrictions will be replaced with the following, including widening access for people with Type 1 diabetes to the dual meter:

BLOOD GLUCOSE DIAGNOSTIC TEST METER

- a) Maximum of 1 pack per prescription
- b) Up to 1 pack available on a PSO
- c) Subsidy by endorsement

A diagnostic blood glucose test meter is subsidised for a patient who:

- 1. is receiving insulin or sulphonylurea therapy; or
- 2. is pregnant with diabetes; or
- 3. is on home TPN at risk of hypoglycaemia or hyperglycaemia; or
- 4. has a genetic or an acquired disorder of glucose homeostasis, excluding type 1 or type 2 diabetes and metabolic syndrome.

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.

Only 1 meter per patient will be subsidised (no repeat prescriptions).

Patients already using the CareSens N POP meter or CareSens N meter are not eligible for a new meter, unless they meet the criteria for a dual blood glucose and blood ketone diagnostic test meter.

For the avoidance of doubt patients who have previously received a funded meter, other than CareSens, are eligible for a funded CareSens meter.

From 1 February 2018 – 31 July 2018 patients who have used a CareSens II blood glucose diagnostic meter and associated strips, as their only blood glucose diagnostic testing meter and strips, are eligible for a new CareSens meter provided they meet the funding criteria.

DUAL BLOOD GLUCOSE AND BLOOD KETONE DIAGNOSTIC TEST METER

- a) Maximum of 1 pack per prescription
- b) Up to 1 pack available on a PSO
- c) Subsidy by endorsement

A dual blood glucose and blood ketone diagnostic test meter is subsidised for a patient who has:

- 1. type 1 diabetes; or
- 2. permanent neonatal diabetes; or
- 3. undergone a pancreatectomy; or
- 4. cystic fibrosis-related diabetes, or
- 5. metabolic disease or epilepsy under the care of a paediatrician, neurologist or metabolic specialist.

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.

Only 1 meter per patient will be subsidised (no repeat prescriptions).

For the avoidance of doubt patients who have previously received a funded meter, other than CareSens, are eligible for a funded CareSens meter.

From 1 February 2018 – 31 July 2018 patients who have used a CareSens II blood glucose diagnostic meter and associated strips, as their only blood glucose diagnostic testing meter and strips, are eligible for a new CareSens meter provided they meet the funding criteria.

BLOOD KETONE DIAGNOSTIC TEST STRIP

- a) Maximum of 20 strips per prescription
- b) Up to 10 strips available on a PSO
- c) Not on a BSO

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Subsidy by endorsement

Patient has any of the following:

- 1. type 1 diabetes; or
- 2. permanent neonatal diabetes; or
- 3. undergone a pancreatectomy; or
- 4. cystic fibrosis-related diabetes; or
- 5. metabolic disease or epilepsy under the care of a paediatrician, neurologist or metabolic specialist

The prescription must be endorsed accordingly.

- A six-month transition period will start on 1 February 2018 and end on 31 July 2018, during which the following fees, notes and rules will apply:
 - A Brand Switch Fee (\$4.50) will be available to be claimed on dispensing by pharmacies, once per patient, for any of the four CareSens meters.
 - The following will be able to be provided by a pharmacist under the nonprescribing Practitioners rules in Part III of Section A:
 - Blood glucose diagnostic test meter; and
 - Dual blood glucose and blood ketone diagnostic test meter.
 - The "No patient co-payment payable" restriction will be applied to the dispensing of the four CareSens meters.

From 1 August 2018:

- The following products will be delisted and their Special Authorities (where relevant) deleted, including:
 - CareSens II blood glucose diagnostic test meter;
 - Accu-Chek Performa, Freestyle Optium and CareSens blood glucose diagnostic test strips; and
 - Freestyle Optium Neo blood ketone diagnostic test meter.
- The following products will have Sole Supply Status until 30 June 2022:
 - CareSens blood glucose diagnostic test meters, dual blood glucose and blood ketone diagnostic test meters, blood ketone diagnostic test meters and blood glucose test strips; and
 - KetoSens blood ketone test strips

Section H (Hospital Medicines List) changes

From 1 February 2018:

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- The following products will be listed (or remain listed) at the prices (ex-man., ex. GST) set out in the table below:
 - CareSens N Premier blood glucose diagnostic test meter;
 - CareSens PRO blood glucose diagnostic test strips;
 - CareSens Dual blood glucose and blood ketone dual testing meter;
 - KetoSens blood ketone test strips;
 - o CareSens N blood glucose diagnostic test meter;
 - o CareSens N POP blood glucose diagnostic test meter; and
 - o CareSens N blood glucose diagnostic test strips.

Pharmaceutical	Presentation	Brand	Pack size	Price
Blood glucose diagnostic test meter	Meter with 50 lancets, a lancing device and 10 blood glucose diagnostic test strips	CareSens N CareSens N POP CareSens N Premier	1 1 1	\$10.00 \$10.00 \$20.00
Blood glucose diagnostic test strip	Test strip	CareSens N CareSens PRO	50 test 50 test	\$10.56 \$10.56
Dual blood glucose and blood ketone diagnostic test meter	Meter with 50 lancets, a lancing device and 10 blood glucose diagnostic test strips	CareSens Dual	1	\$20.00
Blood ketone diagnostic test strip	Test strip	KetoSens	10 test	\$15.50

Please note - All the prices will be subject to a confidential rebate

From 1 August 2018:

- All other brands will be delisted, including:
 - CareSens II, Accu-Chek Performa, Freestyle Lite and On Call Advanced
 blood glucose diagnostic test meters;
 - Accu-Chek Performa, Freestyle Optium, Freestyle Lite, On Call Advanced and CareSens – blood glucose diagnostic test strips;
 - Freestyle Optium Neo blood ketone diagnostic test meter.



Our response to what you told us

We're really grateful for the time people took to respond to this consultation. A summary of the main themes raised in feedback, our responses to the feedback received, and changes we have made after listening to you are available on our <u>notification webpage</u>.

If you have any questions about this decision, you can email us at <u>enquiry@pharmac.govt.nz;</u> or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.