

8 June 2009

Approval of Multiple Diabetes Management Products and Mesalazine proposals

PHARMAC is pleased to announce the approval of five agreements in relation to funding of blood glucose test strips, blood glucose diagnostic test meters, blood ketone test strips, urine ketone test strips, insulin pen needles, disposable insulin syringes, and mesalazine.

Some of the proposals as originally consulted on in our letter dated 18 March 2009 are still under consideration and a notification will be issued when a decision is made.

Summary of the decisions

In relation to blood glucose test strips and blood glucose diagnostic test meters

- Three new brands of blood glucose test strips and blood glucose diagnostic test meters (in addition to those already listed) will be funded:
 - FreeStyle Lite (as supplied by Medica Pacifica);
 - CareSens II (as supplied by Pharmaco); and
 - CareSens POP (as supplied by Pharmaco).
- SensoCard blood glucose test strips (as supplied by Point of Care Diagnostics) will be funded for patients who are severely visually impaired; and
- Funded access to blood glucose diagnostic test meters will be widened to include people with gestational diabetes.

A decision on the proposed funding of the On Call Plus brand of blood glucose test strips and blood glucose diagnostic test meters (as supplied by Diabetes Supplies) is still under consideration. As a consequence, the related proposal to reduce the subsidy, through reference pricing, for the Accu-Chek Performa blood glucose test strips brand (as supplied by Roche Diagnostics) is still under consideration.

In relation to ketone testing

- Optium blood ketone test strips (as supplied by Medica Pacifica) will be funded via an endorsement restriction for people with type 1 diabetes;
- Ketostix (foiled strips) urine ketone test strips (as supplied by Bayer) will be funded; and
- The current, partially subsidised, glucose and/or ketones/urine testing brands will be delisted from the Pharmaceutical Schedule.

In relation to insulin pen needles and disposable insulin syringes

- The subsidy and price for ABM insulin pen needles and disposable insulin syringes (as supplied by ABM Pharma) will reduce;
- SC Profi-Fine insulin pen needles (as supplied by Pharmaco) and DM Ject disposable insulin syringes (as supplied by Pharmaco) will be funded;
- The SC Profi-Fine brand of insulin pen needles and the DM Ject brand of disposable insulin syringes will be subject to a volume related price adjustment, that will result in a price reduction to match that of the ABM brand of insulin pen needles, should SC Profi-Fine and DM Ject (in any total combination) obtain approximately 30% market share; and
- The subsidies for the B-D (as supplied by Becton Dickinson) and NovoFine (as supplied by Novo Nordisk) brands of insulin pen needles and disposable insulin syringes will reduce, through reference pricing, to match that of ABM or SC Profi-Fine (where applicable). This will mean that a manufacturer's surcharge could apply if the prices of B-D and NovoFine are not reduced.

In relation to mesalazine

- The subsidy and price for Pentasa (as supplied by Pharmaco) will reduce;
- The current Retail pharmacy – Specialist restrictions applying to mesalazine preparations will be removed.

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

Details of the decision

In relation to blood glucose diagnostic test strips

- The following blood glucose test strips will be listed (where applicable) in Section B of the Pharmaceutical Schedule from the following dates and at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Form and Strength	Brand	Pack size	Subsidy and price	Listing Date
Blood glucose diagnostic test strip	Blood/glucose test strips	Optium 5 second test	25 test OP	\$10.82	1 July 2009
Blood glucose diagnostic test strip	Blood/glucose test strips	Optium 5 second test	50 test OP	\$21.65	1 July 2009
Blood glucose diagnostic test strip	Blood/glucose test strips	FreeStyle Lite	50 test OP	\$21.65	1 July 2009
Blood glucose diagnostic test strip	Blood/glucose test strips	CareSens II	50 test OP	\$19.25	1 September 2009
Blood glucose diagnostic test strip	Blood/glucose test strips	SensoCard	50 test OP	\$26.20	1 July 2009

Note: The chemical description will be renamed from glucose dehydrogenase to blood glucose diagnostic test strip from 1 July 2009.

- The above brands, excluding SensoCard, will be listed in Part II of Section H of the Pharmaceutical Schedule at the applicable dates and prices.
- The funding for SensoCard blood glucose test strips will be restricted by the following note:

“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.”

In relation to blood glucose diagnostic test 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 the following dates and at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Form and Strength	Brand	Pack size	Subsidy and price	Listing Date
Blood glucose diagnostic test meter	Meter	Optium Xceed	1	\$9.00	1 July 2009
Blood glucose diagnostic test meter	Meter	FreeStyle Lite	1	\$9.00	1 July 2009
Blood glucose diagnostic test meter	Meter	CareSens II	1	\$9.00	1 September 2009
Blood glucose diagnostic test meter	Meter	CareSens POP	1	\$6.00	1 September 2009

- As previously noted, SensoCard Plus Talking Blood Glucose Monitor will not be listed on the Pharmaceutical Schedule. We understand this will continue to be distributed and managed by the Royal New Zealand Foundation for the Blind.
- The current endorsement restriction applying to blood glucose diagnostic test meters will be amended from 1 July 2009 to allow funding for people with gestational diabetes (changes are indicated by bold text):

Subsidy by endorsement.

a) Maximum of 1 meter per prescription.

b) A diagnostic blood glucose test meter is subsidised for patients who begin insulin or sulphonylurea therapy after 1 March 2005 **or is prescribed for a pregnant women with diabetes.**

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

- Subsidy and delisting protection will apply to FreeStyle Lite, Optium, Optium Xceed, CareSens II and Care Sens POP until 30 June 2011 in relation to blood glucose test strips and blood glucose diagnostic test meters.

In relation to ketone testing

- Blood ketone test strips will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following subsidy and price (ex-manufacturer, excluding GST) from 1 July 2009:

Chemical	Form and Strength	Brand	Pack size	Subsidy and price
Ketone blood beta-ketone electrodes	Test strip	Optium Blood Ketone Test Strips	10 strip OP	\$8.50

- Optium Blood Ketone Test Strips will be subject to the following restriction:

“Patient has type 1 diabetes and has had one or more episodes of ketoacidosis (excluding first presentation). Maximum quantity of 2 packs per annum. No further prescriptions will be subsidised.”

- Note that the Optium Blood Ketone Test Strips are only compatible with Optium Xceed blood glucose meters. The Optium Xceed meter is capable of performing both blood glucose and blood ketone testing without the need for repeated calibrations however funding is restricted to one meter per patient; therefore, in cases where patients had initially received a funded Accu-Chek meter, a second Optium Xceed meter will not be funded.
- Urine ketone individually foil wrapped test strips will be listed in Section B of the Pharmaceutical Schedule at the following subsidy and price (ex-manufacturer, excluding GST) from 1 August 2009:

Chemical	Form and Strength	Brand	Pack size	Subsidy and price
Sodium nitroprusside	Test strip	Ketostix	20 strip OP	\$14.14

- Subsidy and delisting protection will apply to Optium Blood Ketone Test Strips until 30 June 2011.
- The following partially subsidised urine ketone test strips will be delisted from Section B of the Pharmaceutical Schedule from 1 December 2009:

Chemical	Form and Strength	Brand	Pack size	Subsidy (Price)
Glucose oxidase	Urine diagnostic test with peroxidase, sodium nitroprusside and aminoacetic acid	Keto-Diabor 5000	50 stick OP	\$4.53 (\$8.00)
Glucose oxidase	Urine diagnostic test with peroxidase, potassium iodide, sodium nitroprusside and aminoacetic acid	Keto-Diastix	50 strip OP	\$4.53 (\$7.50)

Chemical	Form and Strength	Brand	Pack size	Subsidy (Price)
Sodium nitroprusside	Urine diagnostic strips, buffered	Ketur-Test	50 strip OP	\$3.39 (\$6.00)
		Ketostix	50 strip OP	\$3.40 (\$7.15)

- The current Glucose and/or Ketone/Urine Testing therapeutic subgroup will be renamed from 1 July 2009 to Ketone Testing. Both Optium Blood Ketone Test Strips and Ketostix will be listed in this therapeutic subgroup.

In relation to insulin pen needles and disposable insulin syringes

- The following insulin pen needles will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from the following dates and at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Form and Strength	Brand	Pack size	Subsidy and price	Date of Listing
Insulin pen needles	29 g x 12.7 mm	ABM	100	\$10.50	1 July 2009
		SC Profi-Fine	100	\$11.75	1 September 2009
Insulin pen needles	31 g x 5 mm	SC Profi-Fine	100	\$11.75	1 September 2009
Insulin pen needles	31 g x 6 mm	ABM	100	\$10.50	1 July 2009
		SC Profi-Fine	100	\$11.75	1 September 2009
Insulin pen needles	31 g x 8 mm	ABM	100	\$10.50	1 July 2009
		SC Profi-Fine	100	\$11.75	1 September 2009

- The following disposable insulin syringes will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from the following dates and at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Form and Strength	Brand	Pack size	Subsidy and price	Date of Listing
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 29 g x 12.7 mm needle	ABM	100	\$13.00	1 July 2009
		DM Ject	100	\$13.00	1 September 2009
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 31 g x 8 mm needle	ABM	100	\$13.00	1 July 2009
		DM Ject	100	\$13.00	1 September 2009

Chemical	Form and Strength	Brand	Pack size	Subsidy and price	Date of Listing
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 29 g x 12.7 mm needle	ABM	100	\$13.00	1 July 2009
		DM Ject	100	\$13.00	1 September 2009
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 31 g x 8 mm needle	ABM	100	\$13.00	1 July 2009
		DM Ject	100	\$13.00	1 September 2009
Insulin syringes, disposable with attached needle	Syringe 1 ml with 29 g x 12.7 mm needle	ABM	100	\$13.00	1 July 2009
		DM Ject	100	\$13.00	1 September 2009
Insulin syringes, disposable with attached needle	Syringe 1 ml with 31 g x 8 mm needle	ABM	100	\$13.00	1 July 2009
		DM Ject	100	\$13.00	1 September 2009

- The subsidies for B-D Micro-Fine and NovoFine will be reduced to the same level as ABM or SC Profi-Fine (where applicable) through the application of reference pricing, from the following dates as follows:

Chemical	Form and Strength	Brand	Pack size	Current subsidy and price	New subsidy	Change date
Insulin pen needles	29 g x 12.7 mm	B-D Micro-Fine	30	\$3.93	\$3.15	1 July 2009
			100	\$13.09	\$10.50	
Insulin pen needles	31 g x 5 mm	B-D Micro-Fine	100	\$13.09	\$11.75	1 September 2009
Insulin pen needles	31 g x 6 mm	NovoFine	100	\$26.00	\$10.50	1 July 2009
Insulin pen needles	31 g x 8 mm	B-D Micro-Fine	30	\$3.93	\$3.15	1 July 2009
			100	\$13.09	\$10.50	

- The subsidies for B-D Ultra Fine and B-D Ultra Fine II will be reduced to the same level as ABM and DM Ject through the application of reference pricing, from 1 July 2009 as follows:

Chemical	Form and Strength	Brand	Pack size	Current subsidy and price	New subsidy
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 29 g x 12.7 mm needle	B-D Ultra Fine	10	\$1.59 (\$1.99)	\$1.30
			100	\$15.92	\$13.00
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 31 g x 8 mm needle	B-D Ultra Fine II	100	\$1.59 (\$1.99)	\$1.30
			100	\$15.92	\$13.00
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 29 g x 12.7 mm needle	B-D Ultra Fine	10	\$1.59 (\$1.99)	\$1.30
			100	\$15.92	\$13.00

Chemical	Form and Strength	Brand	Pack size	Current subsidy and price	New subsidy
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 31 g x 8 mm needle	B-D Ultra Fine II	10	\$1.59 (\$1.99)	\$1.30
			100	\$15.92	\$13.00
Insulin syringes, disposable with attached needle	Syringe 1 ml with 29 g x 12.7 mm needle	B-D Ultra Fine	10	\$1.59 (\$1.99)	\$1.30
			100	\$15.92	\$13.00
Insulin syringes, disposable with attached needle	Syringe 1 ml with 31 g x 8 mm needle	B-D Ultra Fine II	10	\$1.59 (\$1.99)	\$1.30
			100	\$15.92	\$13.00

- Any supplier affected by the application of reference pricing above needs to notify PHARMAC by 12 June 2009 if it intends on reducing the price of its brand using the relevant product notification form on our website.
- The following price volume adjustment (ex-manufacturer, excluding GST) will apply to SC Profi-Fine and DM Ject based on the products (in any total combination) obtaining 30% market share (at Pharmaco's prices, estimated to equal \$200,000):

Chemical	Form and Strength	Brand	Pack size	Subsidy and price
Insulin pen needles	29 g x 12.7 mm	SC Profi-Fine	100	\$10.50
Insulin pen needles	31 g x 5 mm	SC Profi-Fine	100	\$10.50
Insulin pen needles	31 g x 6 mm	SC Profi-Fine	100	\$10.50
Insulin pen needles	31 g x 8 mm	SC Profi-Fine	100	\$10.50
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 29 g x 12.7 mm needle	DM Ject	100	\$10.50
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 31 g x 8 mm needle	DM Ject	100	\$10.50
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 29 g x 12.7 mm needle	DM Ject	100	\$10.50
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 31 g x 8 mm needle	DM Ject	100	\$10.50
Insulin syringes, disposable with attached needle	Syringe 1 ml with 29 g x 12.7 mm needle	DM Ject	100	\$10.50
Insulin syringes, disposable with attached needle	Syringe 1 ml with 31 g x 8 mm needle	DM Ject	100	\$10.50

- The subsidy for B-D Ultra Fine and B-D Ultra Fine II will be further reduced to match the lower DM Ject prices in the event that its prices are reduced on obtaining 30% market share. An announcement will be made on any such price changes via the Pharmaceutical Schedule.
- Subsidy and delisting protection will apply to ABM, SC Profi-Fine and DM Ject until 30 June 2011.

- The restriction applying to NovoFine pen needles 31 g x 6 mm (subsidised for children under 12 years of age) will be removed from 1 July 2009.

In relation to mesalazine

- The subsidy and price of mesalazine (Pentasa) as listed in Section B of the Pharmaceutical Schedule will be reduced as follows from 1 November 2009 (ex manufacturer and ex GST):

Chemical	Form and Strength	Brand	Pack size	Current subsidy and price	Proposed subsidy
Mesalazine	Tab long-acting 500 mg	Pentasa	100	\$69.06	\$59.05

- Pentasa will be listed in Part II of Section H of the Pharmaceutical Schedule at the applicable price from 1 November 2009.
- A rebate will apply to Pentasa for the period from 1 March 2009 until 30 October 2009. The rebate has the effect of obtaining the lower price for Pentasa for the duration of this period.
- All mesalazine presentations (tablets and enemas) will no longer be subject to a "Retail pharmacy-Specialist" restriction, meaning that prescriptions written by other types of practitioners will no longer require a specialist endorsement for subsidy.
- Subsidy and delisting protection will apply to Pentasa until 30 June 2012.

What feedback was received?

We appreciate the feedback we received and acknowledge the time people took to respond. A variety of consultation responses were received in relation to the proposals and all responses were considered in the decisions on the proposed changes. Some concerns were raised with specific aspects of the proposal and we have outlined those we are able to publicise below, along with our response:

Theme	Response
Support was provided for listing of gestational meters, listing the Sensocard test strip brand, and removing the mesalazine restrictions.	Support noted.
Requests were made that PHARMAC review the funding of lancets.	As mentioned in consultation PHARMAC intends to continue to search for an acceptable method for funding.
Requests were made for funding 0.5 unit insulin syringes for paediatric patients.	PHARMAC was not aware of this issue and intends to investigate.

Theme	Response
Queries were made regarding the suitability and testing of the new brands of insulin pen needles and insulin syringes.	We note that ABM has already been listed for 12 months and that this brand and the Pharmaco brands are standardised to fit the existing insulin pens. Limited field testing has occurred without any significant concerns raised.
Requests that the restriction on the number of blood ketone strips be increased especially for those patients who are using insulin pumps and that ketone test strips are available from diagnosis and not as proposed on presentation of DKA after diagnosis.	Clinical advice from the Diabetes Subcommittee of PTAC was that 2 boxes annually was clinically appropriate (including those patients using insulin pumps) and that they should be restricted to patients that have had one or more episodes of ketoacidosis. We intend to ask the Diabetes Subcommittee to review the restriction at its meeting in August, to ensure that this is still appropriate.
Additional meters would dilute the training and resources for people with diabetes.	We are not proposing to delist the current brands and healthcare professionals can continue to decide to use the current brands only. We note that some responders were positive towards a greater choice of meters.
Requests that more test strips are available for patients with type 2 diabetes.	The Diabetes Subcommittee considered the restriction last year and considered that it is clinically appropriate.
Requests were made for the funding of insulin pump consumables.	Funding of pumps and consumables is a related issue. Insulin pumps are not currently funded on the Pharmaceutical Schedule. We note that the Ministry of Health already provides some funding for insulin pumps to DHBs and is currently reviewing the funding availability.
One pharmacist suggested that all pharmacists should be able to endorse the blood ketone test strip restriction prescriptions.	<p data-bbox="847 1406 1449 1503">There is a wider issue about entitlements to authorise subsidy payments that this proposal was not seeking to address.</p> <p data-bbox="847 1529 1449 1597">We did not consider this change appropriate or necessary at this time.</p>

The Christchurch Diabetes Centre has undertaken a meter evaluation for the new brands of blood glucose test strips and blood glucose diagnostic test meters. The independent study evaluated the accuracy and precision of the meters and showed good performance for all meters under controlled conditions. The performance of these brands appears similar to that of the two meters currently on the New Zealand market (namely the Accu-Chek Performa and Optium Xceed).

Finally, we note that the field testing for the SensoCard Plus blood glucose test strips and blood glucose diagnostic test meter provided positive results.