

08 August 2012

Funding of New Zealand Medical and Scientific Insulin pump and consumables approved

PHARMAC is pleased to announce that the approval of an agreement with New Zealand Medical and Scientific for Animas 2020 insulin pump and consumables. This was the subject of a consultation letter dated 27 February 2012. In summary, the effect of the decision is that:

- Animas 2020 insulin pumps and consumables will be funded from 1 September 2012 through a dual supply agreement with the supplier.
- Special Authority criteria apply and an Insulin Pump panel consisting of 6 clinicians has been established to assess applications.
- Application forms will be available from the PHARMAC website from 1 September 2012 at www.pharmac.govt.nz/SAForms.

Details of the proposal

Animas 2020 (insulin pump) will be listed in the Pharmaceutical Schedule from 1 September 2012 at a price and subsidy of \$4,500.00 per pump (ex-manufacturer, excl. GST) as follows;

Brand name	Presentation	Pack size
Animas 2020	Insulin pump, flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 U/h basal rate; 0.05 U incremental bolus; black colour	1
Animas 2020	Insulin pump, flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 U/h basal rate; 0.05 U incremental bolus; silver colour	1
Animas 2020	Insulin pump, flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 U/h basal rate; 0.05 U incremental bolus; blue colour	1
Animas 2020	Insulin pump, flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 U/h basal rate; 0.05 U incremental bolus; green colour	1
Animas 2020	Insulin pump, flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 U/h basal rate; 0.05 U incremental bolus; pink colour	1

- The following insulin pump infusion sets will be listed in the Pharmaceutical Schedule from 1 September 2012 at the following prices and subsidies (ex-manufacturer, excl. GST);

Brand name	Presentation	Pack	Price and Subsidy (\$)
Comfort Short	Insulin pump infusion set, teflon cannula angle insertion 13 mm; 60 cm grey line x 5 with 10 needles	1 OP	120.00
Comfort	Insulin pump infusion set, teflon cannula angle insertion 17 mm; 60 cm grey line x 5 with 10 needles	1 OP	120.00
Comfort	Insulin pump infusion set, teflon cannula angle insertion 17 mm; 110 cm grey line x 5 with 10 needles	1 OP	120.00
Inset II	Insulin pump infusion set, teflon cannula straight insertion 6 mm; with auto injector; 60 cm grey line x 10 with 10 needles	1 OP	140.00
Inset II	Insulin pump infusion set, teflon cannula straight insertion 6 mm , with auto injector; 60 cm pink line x 10 with 10 needles	1 OP	140.00
Inset II	Insulin pump infusion set, teflon cannula straight insertion 6 mm with auto injector; 60 cm blue line x 10 with 10 needles	1 OP	140.00
Inset II	Insulin pump infusion set, teflon cannula straight insertion 9 mm with auto injector; 60 cm grey line x 10 with 10 needles	1 OP	140.00
Inset II	Insulin pump infusion set, teflon cannula straight insertion 9 mm with auto injector; 60 cm pink line x 10 with 10 needles	1 OP	140.00
Inset II	Insulin pump infusion set, teflon cannula straight insertion 9 mm with auto injector; 60 cm blue line x 10 with 10 needles	1 OP	140.00
Inset II	Insulin pump infusion set, teflon cannula straight insertion 6 mm with auto injector; 110 cm grey line x 10 with 10 needles	1 OP	140.00
Inset II	Insulin pump infusion set, teflon cannula straight insertion 9 mm with auto injector; 110 cm grey line x 10 with 10 needles	1 OP	140.00
Inset 30	Insulin pump infusion set, teflon cannula angle insertion 13 mm with auto injector; 60 cm grey line x 10 with 10 needles	1 OP	140.00
Inset 30	Insulin pump infusion set, teflon cannula angle insertion 13 mm with auto injector; 60 cm pink line x 10 with 10 needles	1 OP	140.00

Brand name	Presentation	Pack	Price and Subsidy (\$)
Inset 30	Insulin pump infusion set, teflon cannula angle insertion 13 mm with auto injector; 60 cm blue line x 10 with 10 needles	1 OP	140.00
Inset 30	Insulin pump infusion set, teflon cannula angle insertion 13 mm with auto injector; 110 cm grey line x 10 with 10 needles	1 OP	140.00

- The following insulin pump reservoirs will be listed in the Pharmaceutical Schedule from 1 September 2012 at the following prices and subsidies (ex-manufacturer, excl. GST);

Brand name	Presentation	Pack	Price and Subsidy (\$)
IR2020	Insulin pump reservoir, cartridge 200 U, luer lock x 10	1 OP	50.00
Paradigm cartridge 1.8	Insulin pump reservoir, paradigm conversion cartridge, luer lock 1.8 ml x 10	1 OP	50.00
Paradigm cartridge 3.0	Insulin pump reservoir, paradigm conversion cartridge, luer lock 3.0 ml x 10	1 OP	50.00

- The following Special Authority criteria apply to the funding of insulin pumps:

Criteria for Subsidy for insulin pump for permanent neonatal diabetes

Initial application - (permanent neonatal diabetes) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for three months for applications meeting the following criteria:

All of the following:

- Patient has permanent neonatal diabetes; and
- a MDI regimen trial is inappropriate; and
- either
 - has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy, or
 - was already on pump treatment prior to 1 September 2012 and had been evaluated by the multidisciplinary team for their suitability for insulin pump therapy at the time of initiating that pump treatment and continues to benefit from pump treatment; and
- Patient/Parent/Guardian has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional), and
- Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care;

Renewal (permanent neonatal diabetes) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for three months for applications meeting the following criteria:

All of the following:

1. Patient is continuing to derive benefit according to the treatment plan agreed at induction and
2. Patient remains fully compliant and transition to MDI is considered inappropriate by the treating physician; and
3. It has been at least 4 years since the last insulin pump received by the patient or, in the case of patients qualifying under previous pump therapy for the initial application; the pump is due for replacement.

Criteria for Subsidy for insulin pump for hypoglycaemia

Initial application (hypoglycaemia) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for three months for applications meeting the following criteria:

All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy; and
2. Either
 - 2.1. All of the following:
 - 2.1.1. has adhered to an intensive MDI regimen using analogue insulin's for at least six months; and
 - 2.1.2. has had four severe unexplained recurrent hypoglycaemic episodes over a six month period either due to hypoglycaemic unawareness or to nocturnal hypoglycaemia; and
 - 2.1.3. has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy, or
 - 2.2. was already on pump treatment prior to 1 September 2012 and initiated pump treatment for recurrent hypoglycaemic episodes due to hypoglycaemic unawareness or to nocturnal hypoglycaemia and showed a reduction in hypoglycaemic events from pump treatment; and
3. has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional), and
4. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care;

Renewal (hypoglycaemia) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for three months for applications meeting the following criteria:

All of the following:

1. Patient is continuing to derive benefit according to the treatment plan agreed at induction of at least a 50% reduction from baseline in hypoglycaemic events; and
2. HbA1c has not increased from baseline; and
3. It has been at least 4 years since the last insulin pump received by the patient or, in the case of patients qualifying under previous pump therapy for the initial application; the pump is due for replacement.

Criteria for Subsidy for insulin pump for HbA1c

Initial application (HbA1c) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for three months for applications meeting the following criteria:

All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy; and
2. Either:
 - 2.1. All of the following:
 - 2.1.1. has adhered to an intensive MDI regimen using analogue insulin's for at least six months; and
 - 2.1.2. has had unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c and in the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment; and

- 2.1.3. has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy, or
- 2.2. was already on pump treatment prior to 1 September 2012 and had unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c and has reduced HbA1c by at least 10 mmol/mol using insulin pump treatment; and
- 3. has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional), and
- 4. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care;

Renewal (HbA1C) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for three months for applications meeting the following criteria:

All of the following:

- 1. Patient is continuing to derive benefit according to the treatment plan agreed at induction of achieving and maintaining a reduction in HbA1c from baseline of 10 mmol/mol; and
- 2. the number of severe unexplained recurrent hypoglycaemic episodes has not increased from baseline; and
- 3. It has been at least 4 years since the last insulin pump received by the patient or, in the case of patients qualifying under previous pump therapy for the initial application; the pump is due for replacement.

The following Special Authority criteria apply to the funding of insulin pump consumables:

Criteria for Subsidy for insulin pump consumables for permanent neonatal diabetes

Initial application (permanent neonatal diabetes) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for nine months for applications meeting the following criteria:

All of the following:

- 1. Patient has permanent neonatal diabetes; and
- 2. a MDI regimen trial is inappropriate; and
- 3. either
 - 3.1. has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy, or
 - 3.2. was already on pump treatment prior to 1 September 2012 and had been evaluated by the multidisciplinary team for their suitability for insulin pump therapy at the time of initiating that pump treatment and continues to benefit from pump treatment; and
- 4. Patient/Parent/Guardian has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional), and
- 5. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care;

Renewal for (permanent neonatal diabetes) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for two years for applications meeting the following criteria:

All of the following:

- 1. Patient is continuing to derive benefit according to the treatment plan agreed at induction; and
- 2. Patient remains fully compliant and transition to MDI is considered inappropriate by the treating physician.

Criteria for Subsidy for insulin pump consumables for hypoglycaemia

Initial application (hypoglycaemia) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for nine months for applications meeting the following criteria:

All of the following

1. Patient has type 1 diabetes or has undergone a pancreatectomy; and
2. Either:
 - 2.1. All of the following:
 - 2.1.1. has adhered to an intensive MDI regimen using analogue insulin's for at least six months; and
 - 2.1.2. Has had four severe unexplained recurrent hypoglycaemic episodes over a six month period either due to hypoglycaemic unawareness or to nocturnal hypoglycaemia; and
 - 2.1.3. has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy, or
 - 2.2. was already on pump treatment prior to 1 September 2012 and initiated pump treatment due to recurrent hypoglycaemic episodes due to hypoglycaemic unawareness or due to nocturnal hypoglycaemia and showed a reduction in hypoglycaemic events from pump treatment; and
3. has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional), and
4. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care;

Renewal for hypoglycaemia only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for two years for applications meeting the following criteria:

All of the following:

1. Patient is continuing to derive benefit according to the treatment plan agreed at induction of at least a 50% reduction from baseline in hypoglycaemic events; and
2. HbA1c has not increased from baseline

Criteria for Subsidy for insulin pump consumables for HbA1c

Initial application (HbA1c) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for nine months for applications meeting the following criteria:

All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy; and
2. Either:
 - 2.1. All of the following
 - 2.1.1. has adhered to an intensive MDI regimen using analogue insulin's for at least six months; and
 - 2.1.2. has had unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c and in the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment; and
 - 2.1.3. has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy, or
 - 2.2. was already on pump treatment prior to 1 September 2012 unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c and has reduced HbA1c by at least 10 mmol/mol using insulin pump treatment; and
3. has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional), and
4. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care;

Renewal (HbA1C) only from a relevant Specialist or Nurse Prescriber working within their vocational scope. Approvals valid for two years for applications meeting the following criteria:

All of the following:

1. Patient is continuing to derive benefit according to the treatment plan agreed at induction, achieving and maintaining a reduction in HbA1c from baseline of 10 mmol/ml; and
2. the number of severe unexplained recurrent hypoglycaemic episodes has not increased from baseline.

The following restrictions will apply to the dispensing of insulin pumps and consumables as follows:

- Maximum of one insulin pump per prescription, per patient in each four year period.
- Maximum of 3 infusion set packs and reservoir packs per 90 days, with funding for one additional pack per year (13 packs per year).
- Maximum of one battery cap per 180 days.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 16 March 2012 were considered in their entirety in making a decision on the proposed changes. Many responses were supportive of the proposal. The main themes identified during the consultation process were:

- How do patients who are already on a pump access a funded insulin pump and the warranty issues related to using other consumables with a current pump.
- Issues relating to sole supply and patient choice.
- Issues relating to the entry and renewal criteria.

A full summary of the consultation feedback for the insulin pump proposal can be viewed at www.pharmac.govt.nz/diabetes

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.

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.