CONSULTATION

PHARMAC
Pharmaceutical Management Agency

1 September 2015

Proposal to transition funded access to insulin pumps and consumables to a standard Special Authority

PHARMAC is seeking feedback on a proposal to transition the process for obtaining funded access to insulin pumps and consumables from the Insulin Pump Panel to a standard Special Authority from 1 March 2016.

The proposal involves the continuation of funding of insulin pumps and consumables for eligible patients; the main change would be to the mechanism of application for funding.

In summary, from 1 March 2016 this proposal would result in:

- Disestablishment of the Insulin Pump Panel.
- Access to funded insulin pumps and consumables becoming subject to Special Authority criteria to be listed in Section B of the Pharmaceutical Schedule.

Applications for insulin pumps and consumables could be made either electronically, via the electronic Special Authority system, or manually on the Special Authority forms available on the PHARMAC website at www.pharmac.govt.nz/SAForms.

How to provide feedback

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Tuesday, 29th September 2015** to:

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Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive,

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confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request

Background to the proposal

PHARMAC began funding insulin pumps and consumables for eligible patients on 1 September 2012. Access to funding has been through application to the Insulin Pump Panel (IPP).

The IPP was established with the understanding that the funding criteria for insulin pumps and consumables and the process by which health professionals could apply on behalf of their patients for access to funded insulin pumps and consumables would be reviewed after 24 months.

Currently, relevant specialists or nurse prescribers working within their vocational scope can apply to the IPP for funded access to insulin pumps and consumables. The IPP determines whether applications meet the access criteria approved by the PHARMAC Board.

Those criteria currently targeted funding for insulin pumps and consumables to patients living with Type 1 diabetes who have significant instability of glycaemic control, despite optimum treatment with a multiple daily injection (MDI) regimen with insulin analogues. The aim of funded insulin pump therapy is to either reduce the number and frequency of severe hypoglycaemic events and/or to enable improved blood glucose control and reduction of Haemoglobin A1c (HbA1c).

PHARMAC is proposing to transition access to funded insulin pumps and consumables to a standard Special Authority. This would provide a more streamlined mechanism for clinicians and nurse prescribers working within their vocational scope to apply for funded insulin pump therapy for their patients.

Details of the proposal

The proposal involves the continuation of funding of insulin pump and consumables for eligible patients. PHARMAC does not anticipate any alterations to the group of patients who are currently eligible for funded access as a result of this change in the mechanism of application.

The following two brands of insulin pumps and their consumables are funded:

- Animas Vibe
- Paradigm 522 or 722

PHARMAC sought advice from the Diabetes Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) in May 2015 in developing this proposal. The Committee recommended transferring funded access to insulin pump and consumables to a standard Special Authority that would contain new, but similar, criteria.

There are minor changes proposed to the criteria used by the IPP, including the addition of an eligible range of HbA1c values as a further measureable outcome. Having measureable outcomes in the criteria would provide greater certainty that patients would continue to receive benefit from treatment and would ensure the cost effectiveness of insulin pump

therapy. As part of the application, a determination of the patient's suitability for an insulin pump would need to be made.

Key proposed amendments include:

- Detailing suitable HbA1c ranges in both the hypoglycaemic and HbA1c categories.

- Including a category for people who have accessed pump therapy prior to 1 September 2012.

PHARMAC proposes to transition funded access to insulin pumps and consumables from the IPP to a Special Authority on 1 March 2016.

What would change for Prescribers?

The proposal would not change the prescribers eligible to apply for insulin pumps and consumables. Relevant specialists and nurse prescribers working within their vocational scope would be able to continue to apply for funding.

Please note that the term 'relevant specialist' includes vocationally registered General Practitioners as well as other vocationally registered medical practitioners and the term 'Nurse Prescriber' only applies to Nurse Practitioners with a scope of practice of diabetes.

Relevant specialists would be able to apply for Special Authorities through the online Special Authority system, or manually. Applications processed online would get an instant electronic response (approval or decline), where manual applications take up to 10 working days to be processed.

Proposed Criteria

PHARMAC is proposing the following Special Authority criteria for insulin pumps and consumables from 1 March 2016:

Insulin Pumps

Initial application — (**permanent neonatal diabetes)** only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. The patient has permanent neonatal diabetes; and
2. A multiple daily injection (MDI) regimen trial is inappropriate; and
3. Either:
    3.1. The patient has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; or
    3.2. The patient 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. The patient/parent/guardian has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
5. The 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 prescribers working within their vocational scope. Approvals valid for 3 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 four 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.

Initial application — (**severe unexplained hypoglycaemia**) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1. The applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
2. The patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
3. The patient has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
4. The patient has adhered to an intensive multiple daily injection (MDI) regimen using insulin analogues for at least six months; and
5. The patient has had four severe unexplained hypoglycaemic episodes over a six month period (severe as defined as requiring the assistance of another person); and
6. In the opinion of the treating clinician, the number of severe unexplained hypoglycaemic episodes could be reduced by 50% using insulin pump treatment and
7. The patient has an average Haemoglobin A1c (HbA1c) between the following range: equal to or greater than 53 mmol/mol and equal to or less than 90 mmol/mol; and
8. The patient has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy.

Renewal — (severe unexplained hypoglycaemia) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 3 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 severe unexplained hypoglycaemic events (severe as defined as requiring the assistance of another person); and
2. HbA1c has not increased by more than 5 mmol/mol from baseline; and
3. Either:
    - 3.1 It has been at least four years since the last insulin pump received by the patient or;
    - 3.2 The pump is due for replacement.

Initial application — (**HbA1c**) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
2. The patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
3. The patient has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and

4. The patient has adhered to an intensive multiple daily injection (MDI) regimen using insulin analogues for at least six months; and
5. The patient has unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce Haemoglobin A1c (HbA1c; and
6. In the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment; and
7. The patient has typical HbA1c results between the following range: equal to or greater than 65 mmol/mol and equal to or less than 90 mmol/mol; and
8. The patient has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy.

Renewal — (HbA1c) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 3 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/ml; and
2. The number of severe unexplained hypoglycaemic episodes has not increased from baseline; and
3. Either:
    3.1. It has been at least four years since the last insulin pump received by the patient or;
    3.2. The pump is due for replacement.

Initial application — (**Previous use before 1 September 2012**) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. The patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
2. The patient has adhered to an intensive multiple daily injection (MDI) regimen using insulin analogues for at least six months prior to initiating pump therapy; and
3. The patient is continuing to derive benefit from pump therapy; and
4. The patient had achieved and is maintaining a Haemoglobin A1c (HbA1c of equal to or less than 80 mmol/mol on pump therapy; and
5. The patient has had no increase in severe unexplained hypoglycaemic episodes from baseline; and
6. The patient's HbA1c has not deteriorated more than 5 mmol/mol from baseline; and
7. Either:
    7.1. It has been at least four years since the last insulin pump received by the patient or;
    7.2. The pump is due for replacement.

Renewal — (**Previous use before 1 September 2012**) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. The patient is continuing to derive benefit according to the treatment plan and has maintained a HbA1c of equal to or less than 80 mmol/ml; and
2. the patient's HbA1c has not deteriorated more than 5 mmol/ml from the time of commencing pump treatment; and
3. The patient has not had an increase in severe unexplained hypoglycaemic episodes from baseline; and
4. Either:
    4.1. It has been at least four years since the last insulin pump received by the patient or;

4.2. The pump is due for replacement.

Insulin pump consumables

Initial application — (**permanent neonatal diabetes)** only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

1. The patient has permanent neonatal diabetes; and
2. A Multiple Daily Injection (MDI) regimen trial is inappropriate; and
3. Either:
    3.1. The patient has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy, or
    3.2. The patient 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. The patient/parent/guardian has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
5. The 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 prescribers working within their vocational scope. Approvals valid for 2 years for applications meeting the following criteria:
Both:

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

Initial application — (**severe unexplained hypoglycaemia**) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

1. The applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
2. The patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
3. The patient has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
4. The patient has adhered to an intensive Multiple Daily Injection (MDI regimen using analogue insulins for at least six months; and
5. The patient has had four severe unexplained hypoglycaemic episodes over a six month period either due to hypoglycaemic unawareness or to nocturnal hypoglycaemia; and
6. In the opinion of the treating clinician, the number of severe unexplained hypoglycaemic episodes could be reduced by 50% using insulin pump treatment and
7. The patient has an average Haemoglobin A1c (HbA1c between the following range: equal to or greater than 53 mmol/mol and equal to or less than 90 mmol/mol; and
8. The patient has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy.

Renewal — (severe unexplained hypoglycaemia) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 2 years for applications meeting the following criteria:
Both:

1. The patient is continuing to derive benefit according to the treatment plan agreed at induction of at least a 50% reduction from baseline in severe unexplained hypoglycaemic events (severe as defined as requiring the assistance of another person); and
2. HbA1c has not increased from baseline by more than 5 mmol/mol.

Initial application — (**HbA1c**) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

1. The applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
2. The patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
3. The patient has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
4. The patient has adhered to an intensive Multiple Daily Injection (MDI regimen using analogue insulin~~s~~ for at least six months; and
5. The patient has unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce Haemoglobin A1c (HbA1c; and
6. In the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment and this is the treatment plan agreed to with the patient; and
7. The patient has typical HbA1c results between the following range: equal to or greater than 65 mmol/mol and equal to or less than 90 mmol/mol; and
8. The patient has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy.

Renewal — (HbA1c) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 2 years for applications meeting the following criteria:
Both:

1. The 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/ml; and
2. The number of severe unexplained hypoglycaemic episodes has not increased from baseline.

Initial application — (**Previous use before 1 September 2012**) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:

1. The patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
2. The patient has adhered to an intensive Multiple Daily Injection (MDI regimen using insulin analogues for at least six months prior to initiating pump therapy; and
3. The patient is continuing to derive benefit from pump therapy; and
4. The patient has achieved and is maintaining a HbA1c of equal to or less than 80 mmol/mol on pump therapy; and
5. The patient has had no increase in severe unexplained hypoglycaemic episodes from baseline; and
6. The patient's HbA1c has not deteriorated more than 5 mmol/mol from baseline.

Renewal — (**Previous use before 1 September 2012**) only from a relevant specialist or nurse prescribers working within their vocational scope. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:

1. The patient is continuing to derive benefit according to the treatment plan and has maintained a HbA1c of equal to or less than 80 mmol/ml; and
2. The patient's HbA1c has not deteriorated more than 5 mmol/ml from the level at the time the initial application was made; and
3. The patient has not had an increase in severe unexplained hypoglycaemic episodes from the level at the time the initial application was made.