Diabetes Subcommittee of PTAC
Meeting held 16 April 2015

(minutes for web publishing)

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Note that this document is not necessarily a complete record of the Diabetes Subcommittee meeting; only the relevant portions of the minutes relating to Diabetes Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Diabetes Subcommittee may:

a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 13 & 14 August 2015, a record of which will be available in October 2015.

1 Anti-diabetic Agents Request for Information

1.1 The Subcommittee noted that on the 12 February 2015, PHARMAC issued a Request for Information (RFI) to suppliers, clinicians and diabetes health care professionals for the following anti-diabetic agents:

- dipeptidyl peptidase-4 inhibitors (DPP4-inhibitors);
- glucagon-like peptide-1 agonists (GLP-1s);
- sodium glucose co-transporter 2 inhibitors (SGLT-2s); and
- combination anti-diabetic agents (e.g. DPP4-inhibitors/metformin).

1.2 The Subcommittee noted that the RFI closed on 12 March 2015 and PHARMAC had received six supplier responses and fifteen clinician and health professional responses.

1.3 The Subcommittee noted that the majority of clinician and health professional RFI respondents commented they should be able to co-prescribe an anti-diabetic agent with insulin. Members considered there may be approximately 600 patients who could be co-prescribed a new agent with insulin at present and this number could increase by 10% every year.

Members further considered that there were two identifiable patient populations who would receive an additional clinical benefit from insulin co-prescribing:

- Those patients who were insulin resistant, indicated by requiring an insulin dose > 1.5u/kg
- Those patients initiating insulin therapy and taking one of the new agents

1.4 The Subcommittee further considered that there was a small group of patients who were non-compliant with insulin and may 'switch back' to an oral anti-diabetic agent.

1.5 The Subcommittee considered that it may be clinically preferable to co-prescribe insulin with the new agents to reduce the total insulin dosage required for a patient. Members noted that the absolute HbA1C reduction was unlikely to be different with insulin alone versus new agent in combination with insulin. The Subcommittee noted that there was no clinical reason to restrict access to an anti-diabetic agent to those who are not co-prescribed insulin, however, there may be a fiscal rationale for this decision. The Subcommittee noted that this excluded the two groups identified above where there was a clinical need.

1.6 The Subcommittee noted that there were recent published papers about co-prescribing insulin with an anti-diabetic agent. Members considered that a reduction in blood pressure and relative weight loss would be the clinical benefits of co-prescribing. Members noted that few of the papers are independent and many are supported by pharmaceutical companies.

1.7 The Subcommittee considered that as part of any restriction there should be the provision for the new anti-diabetic agents to be co-prescribed with insulin for 3 months to allow for appropriate initiation of insulin. Members further considered those patients who are insulin resistant would need to continue on the anti-diabetic agents.

1.8 The Subcommittee noted that several responders to the RFI provided feedback that the proposed Special Authority (SA) criterion regarding HbA1c values was too restrictive. Members considered that this criterion could be changed to a percentage change in HbA1c as opposed to an absolute value, as a more appropriate indicator.

1.9 Members considered that it would not be clinically reasonable to limit funding to only those patients for whom a reduction in HbA1c of 5 mmol would achieve the HbA1c target for that patient. The Subcommittee considered that the reduction in HbA1C would be greater for those patients who had a higher HbA1C on initiation. Members considered that a 10% reduction in HbA1C would likely provide a significant health benefit to patients.

1.10 The Subcommittee noted that a supplier response to the RFI had proposed new SA criteria for those with a high BMI. Members noted that the proposed access criteria would have excluded the DPP4 class for patients with a BMI of ≥ 35 kg/m$_2$ as RCTs indicated this class showed poor efficacy in this particular patient group. Members considered the data suggested a study bias as the group comparators were an Asian versus a European cohort. Members further considered many published papers include patients with a BMI of ≥ 35 kg/m$_2$ and there is a lack of data to support the supplier's criteria.

1.11 The Subcommittee considered that in response to the RFI feedback the proposed SA criteria be revised as follows (additions in bold and deletions in strikethrough):

> Initial application from any medical practitioner. Approvals valid for six months for applications meeting the following criteria:
>
> 1. Either:
>
> 1.1. Patient is not achieving effective control of HbA1c despite treatment with maximum tolerated doses of metformin and sulphonylurea for at least 6 months; or
>
> 1.2. Patient is not achieving target HbA1c despite treatment with maximum tolerated doses of sulphonylurea and metformin is contraindicated; or
>
> 1.3. Patient is not achieving target HbA1c on maximum tolerated doses of metformin for the previous 6 months and is unable to use insulin or sulphonylureas because the risk of severe symptomatic hypoglycaemia is unacceptable in the opinion of the treating physician; or
>
> ~~2.~~ ~~Patient is not prescribed insulin~~ **Patient is on high dose insulin (>1.5u/kg) with an HbA1c ≥ 70 and at least a 10% reduction in HbA1c can be expected with a new agent.**
>
> ~~3. It is anticipated that a reduction in HbA1c of 5 mmol/mol would achieve the HbA1c target for that patient~~**Patient has an HbA1c of ≥ 65 mmol, on maximum tolerated doses of metformin or sulphonylureas and at least a 10% reduction in HbA1c can be expected with a new agent.**

Renewal from any medical practitioner. Approvals valid for two years for applications meeting the following criteria:

1. ~~Patient has achieved an HbA1c reduction of at least 5 mmol/mol from baseline and;~~ **Patient has achieved a 10% reduction in HbA1c after 12 months; or**
2. ~~Patient is not prescribed insulin~~ **Patient is transitioning to insulin and can be approved for a further 3 months**

1.12 The Subcommittee considered the recent safety concerns highlighted by the FDA with respect to all classes of the new anti-diabetic agents. Members considered that the FDA will shortly publish a report about the new adverse drug reactions associated with these classes. Members discussed that similar safety signals had occurred and resulted in published evidence about the glitazones and that this could be a cause for concern with these new agents.

1.13 The Subcommittee noted the responses to the RFI from clinicians regarding agent preference. The Subcommittee considered that it was not clinically reasonable to fund only one class of anti-diabetic agents. One class would be suitable to fund the majority of patients but a second agent from a second class is required for the remaining patients.

1.14 The Subcommittee **recommended** funding of at least one chemical from two of the three new classes of anti-diabetic agents, DDP4s, GLP-1s or SGLT2s.

1.15 The Subcommittee considered that it would be clinically reasonable for patients to switch within a class of anti-diabetic agents.

1.16 The Subcommittee considered that it would only be reasonable for patients to switch between classes if there is a clinical reason. Members further considered that the clinical reasons patients may switch could, for example, be due to efficacy or tolerability of medication.

1.17 The Subcommittee considered that the current PHARMAC estimates of patient numbers who would be prescribed the anti-diabetic agents were too low. Members noted that there had been significant uptake of the DPP4s and the combination agents in Australia and if the anti-diabetic agents were funded in NZ a similar trend would likely occur.

1.18 The Subcommittee considered that combination agents with metformin would have significant advantages in terms of patient adherence to treatment and convenience of treatment.

2 Insujet Needleless Injection Device

Application

2.1 The Subcommittee considered an application from Pharmaco (NZ) Ltd for the funding of the Insujet Administration System for people with diabetes requiring insulin.

Recommendation

2.2 The Subcommittee **deferred making a recommendation** regarding the application to fund the Insujet Administration System for people with diabetes requiring insulin. Members considered they required further evidence comparing Insujet to psychotherapy for managing needle phobia, in order to make a recommendation.

Discussion

2.3 The Subcommittee considered the application for Insujet needleless injection device was proposed for the following population groups:

- People with Type 1 or Type 2 diabetes who are on insulin and who have a needle phobia that has an adverse effect on compliance of their insulin regime;
- People with Type 2 diabetes who have delayed transition to insulin therapy due to needle phobia;
- Paediatric patients with diabetes for who needle phobia may have an adverse effect on patient compliance to insulin or delay the transition to insulin;
- Pregnant women with gestational diabetes who have a needle phobia;
- Any person with diabetes or their carers, with a preference for a needleless delivery system due to personal comfort or reducing the risk of needle stick injury.

2.4 The Subcommittee considered that the device had an approximate two year life span based on the use of InsuJet being three times a day. Members further considered that the number of consumables associated with use of this device was substantial.

2.5 The Subcommittee noted that the InsuJet is compatible with all brands and types of 3 ml insulin cartridges and 10 ml insulin vials via the use of an adaptor. Members noted that consumable products (nozzle and adaptor) were required as part of the InsuJet device and that an initial supply of the consumables came with the device. Members considered that nozzles required replacement every seven days and the adaptor needs replacing every time a new cartridge or vial is required. Members also noted that the device required reloading for each dose of insulin administered, and that the time taken to load the device was longer than that taken for a syringe, needle and vial.

2.6 The Subcommittee noted that the device administers a single dose of insulin and the dose range was 4-40 international units. Members considered that patients on larger doses of insulin would require multiple loading of insulin and additional consumables. Members further considered that multiple loading of insulin may shorten the ‘life-span’ of the device.

2.7 The Subcommittee considered a double blind, double dummy RCT that compared the pharmacologic profile of insulin aspart by jet injection to that by conventional pen injection (Engwerda E., Abbink E et al., Diabetes Care 2011, 34;(8):1804-1808) which concluded that that administration of insulin with Insujet instead of a conventional insulin pen can achieve a more rapid onset of insulin action, halving the time to reach maximal glucose lowering effect. Members noted however that the trial used healthy participants and needed to be replicated in patients with diabetes. The Subcommittee considered that the evidence provided to support similar pharmacodynamic and pharmacokinetic effects of rapid acting insulin when administered by the Insujet compared to a conventional pen to be reasonable, however, there was no evidence provided to suggest that the reported increased absorption of insulin provided any additional clinical benefit.

2.8 The Subcommittee considered the survey results of patients with Type 2 Diabetes who were insulin naïve and were recently prescribed insulin and their degree of adherence or non-adherence to therapy (Karter A et al, Diabetes Care 2010, 33;(4): 733-735). Members noted that there were no findings from the survey that concluded a needleless injection device would support patient compliance. Members noted that of the 169 patients surveyed, 69 were non-adherent and 13% of those patients reported needle phobia as there reason to be non-adherent. Members considered that clinicians experience fewer patients with needle phobia than the number stated in the study.

2.9 The Subcommittee considered that there was very little evidence provided in the survey by Karter A et al, Diabetes Care 2010, 33 ;(4): 733-735 to support that the insulin administration system helped patients to manage their needle phobia compared to a conventional insulin pen. Members further considered that the insulin administration system would provide the same health benefits as insulin administered via a needle and syringe or insulin pen.

2.10 Members considered that current clinical practice was to refer patients with needle phobia to a nurse educator or a clinical psychologist if needed. Members considered that most patients presenting with needle phobia can overcome their fear with gentle persuasion, nurse education and support. The Subcommittee considered that true needle phobia was rare and that anecdotally clinical psychologists have a high rate of success to assist patients to overcome needle phobia.

2.11 The Subcommittee considered it would be useful to know how many current users of the insulin administration system there are in New Zealand and Australia. Members requested PHARMAC source this information.

2.12 The Subcommittee noted that the device may reduce the risk of needle stick injury for administrators.

2.13 The Subcommittee considered that paediatric patients, or their caregivers, with needle phobia would benefit the most from this insulin administration system. Members considered that there was insufficient evidence of associated increased compliance for this group.

2.14 The Subcommittee considered that the use of this insulin administration system would result in additional prescription charges due to the requirement for nozzles and syringes and additional nursing costs associated with patient education to use the device

2.15 The Subcommittee considered that the use of this insulin administration system would most likely result in a small drop in demand for needles/syringes, however members considered that the cost of needles/syringes was substantially less than the consumables for the InsuJet and therefore this would likely result in an overall increase in expenditure.

2.16 The Subcommittee noted that this was a supplier generated application and that to date PHARMAC had received no NPPA applications for an insulin administration system. Members considered that the proportion of users who would have otherwise avoided insulin entirely or who are actually not choosing to commence insulin because of needles would be small. Members further considered that for those patients who use injectable insulin but are not fully compliant or do not use it correctly Insujet would not provide benefit for them.

3 Insulin Pump Panel Transition to Special Authority

3.1 The Subcommittee reviewed a request from PHARMAC staff for advice on appropriate Special Authority (SA) criteria for funding of insulin pumps and consumables, in place of the Insulin Pump Panel. Members noted that this review was in place of the recommendation from the previous meeting to reconvene via teleconference.

3.2 The Subcommittee noted that the Insulin Pump Panel reviews 10-15% of insulin pump applications and approves approximately 97% of applications.

3.3 The Subcommittee noted that patient numbers were higher than originally predicted and that the numbers appear to have been underestimated by approximately 25%. Members further noted that the majority of applications were for the severe hypoglycaemia criteria rather than the HbA1c criteria. Members considered this may possibly be due to renewal criteria for severe hypoglycaemia being easier to meet than the HbA1c criteria and this is anticipated by applicants at the time of initial application.

3.4 The Subcommittee considered that a SA for insulin pumps and consumables would not create any significant changes in health sector expenditure other than for direct treatment costs Members further considered that the direct treatment costs would not significantly increase as 97% of insulin pump applications currently reviewed by the panel are approved. The Subcommittee further considered that a Special Authority for insulin pumps and consumables might reduce health sector workloads due to less paperwork being required.

3.5 The Subcommittee considered that the current criteria has provided access for patients to insulin pumps and consumables as initially intended with the exception of a group of patients who have lower HbA1c levels who would still benefit from a pump and a group of patients with significant dawn phenomenon.

The Subcommittee considered that patients with a high HbA1c should not be included in the funded population. Members further considered an upper limit of HbA1c of 90 would be appropriate on the SA.

3.6 The Subcommittee **recommended** the following changes to their initial proposed criteria for insulin pumps and consumables on Special Authority:

Insulin Pumps

Initial application — (**permanent neonatal diabetes)** only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. Approvals valid for 3 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 — (permanent neonatal diabetes) only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. 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 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.

Initial application — (**severe unexplained hypoglycaemia**) only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
2. Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
3. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
4. Has adhered to an intensive MDI regimen using analogue insulin's for at

least six months; and

5. All of the following:
    5.1. Has had four severe unexplained hypoglycaemic episodes over a six month period (severe as defined as requiring the assistance of another person); and
    5.2. Has an average HbA1c between the following range: equal to or greater than 53 mmol/mol and equal to or less than 90 mmol/mol; and
    5.3. 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 Prescriber on the recommendation of a relevant Specialist. 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 5mmol/mol from baseline; and
3. Either:
    3.1 It has been at least 4 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 Prescriber on the recommendation of a relevant Specialist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
2. Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
3. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care.
4. Has adhered to an intensive MDI regimen using analogue insulin's for at least six months; and
    4.1. Has unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c; and
    4.2. In the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment; and
    4.3. 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
    4.4. Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy.

Renewal — (HbA1c) only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. 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 4 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 Prescriber on the recommendation of a relevant Specialist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. 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 MDI regimen using analogue insulin's 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 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 4 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 Prescriber on the recommendation of a relevant Specialist. 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 fromthe 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 4 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 Prescriber on the recommendation of a relevant Specialist. Approvals valid for 9 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 — (permanent neonatal diabetes) only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. Approvals valid for 2 years for applications meeting the following criteria:
Both:

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.

Initial application — (**severe unexplained hypoglycaemia**) only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
2. Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
3. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
4. Has adhered to an intensive MDI regimen using analogue insulins for at least six months; and
5. All of the following;
    5.1. Four severe unexplained hypoglycaemic episodes over a six month period either due to hypoglycaemic unawareness or to nocturnal hypoglycaemia; and
    5.2. An average HbA1c between the following range: equal to or greater than 53 mmol/mol and equal to or less than 90 mmol/mol; and
    5.3. 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 Prescriber on the recommendation of a relevant Specialist. Approvals valid for 2 years for applications meeting the following criteria:
Both:

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 from baseline by more than 5 mmol/mol.

Initial application — (**HbA1c**) only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

1. Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
2. Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
3. Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
4. Has adhered to an intensive MDI regimen using analogue insulin~~'s~~ for at least six months; and
5. All of the following:
    5.1. Has unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c; and
    5.2. in the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment; and
    5.3. 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
    5.4. Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy.

Renewal — (HbA1c) only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. Approvals valid for 2 years for applications meeting the following criteria:
Both:

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.

Initial application — (**Previous use before 1 September 2012**) only from a relevant Specialist or Nurse Prescriber on the recommendation of a relevant Specialist. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:

1. 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 MDI regimen using analogue insulin's 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 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 Prescriber on the recommendation of a relevant Specialist. 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 initial application; and
3. The patient has not had an increase in severe unexplained hypoglycaemic episodes from baseline

3.7 The Subcommittee noted that PHARMAC receives approximately 5 initial insulin pump applications per month for 'grandparent patients' and would expect a maximum of approximately 120 applications over the next 2 years.

3.8 The Subcommittee considered that the definition of severe hypoglycaemia is appropriate for both adults and paediatric patients. Members considered that the majority of paediatric patients would be likely to meet the severe hypoglycaemia criteria because they require assistance from another to manage the hypoglycaemia.

3.9 The Subcommittee noted that there have been a number of patients that have not met the renewal criteria for consumables and have subsequently been assessed by the Panel. The Subcommittee further considered some of these patients had been provided a 9 month 'stand-down period' to enable them time to meet renewal criteria. The Subcommittee considered that patients under the HbA1c criteria should not be approved a 9 month extension of consumables if they haven't met the 10 mmol HbA1c reduction target. Members noted that in this instance applicants could have access to the consumables for their patients via SA waiver and should be considered on a case by case basis.

3.10 The Subcommittee noted that Vocationally Registered General Practitioners (VRGP) are eligible applicants for the Special Authority criteria. Members considered that VRGP would most likely be aware that they are now classed as specialists within the Pharmaceutical Schedule rules. Members further considered that when the SA is implemented an appropriate implementation activity would be to highlight who is included as a VRGP.

3.11 The Subcommittee **recommended** that PHARMAC should advise the NZSSD, BPAC and RNZCGP and write to all previous applicants if the IPP is disestablished and a Special Criteria is initiated.

3.12 The Subcommittee **recommended** PHARMAC action their request at the previous Diabetes Subcommittee meeting which was to compare clinical outcomes (HbA1c, hypoglycaemic episodes) at renewal versus baseline and present this to the Diabetes Subcommittee for comments. Members considered that this would assist informing recommendations on thresholds and whether these should these be reviewed in future.

3.13 The Subcommittee noted that the insulin pump CUA measuring the quality of life impact of ongoing severe hypoglycaemia for patients with diabetes has not been included in the modelling. The Subcommittee considered that a comparison of hypoglycaemia to that of severe epilepsy could be investigated in the CUA model.

4 Blood Glucose Meters

4.1 The Subcommittee noted that the sole-supply period for blood glucose meters and test strips ends on 30 June 2015. Members noted that at the February 2012 meeting they had considered that offering a range of meters would be important. The Subcommittee noted in April PHARMAC had completed an initial consultation of the proposed approach to funding blood glucose meters. Members noted 313 responses were received. The Subcommittee noted that the next steps in this process will be the issuing of a Request for Information (RFI) in May/June to all interested suppliers.

4.2 The Subcommittee considered that software download capability of blood glucose meters is an important feature. Members further considered that a web based programme or an application (app) may be a useful feature of a future funded meter.