

**Diabetes Subcommittee of PTAC**  
**Meeting held 19 March 2019**

**(minutes for web publishing)**

Diabetes Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2016*.

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 will be reviewed by PTAC at its meeting 23 and 24 May 2019, the record of which will be available in due course.

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## 1. Correspondence and Matters Arising

### *Correspondence from NZSSD*

- 1.1. The Subcommittee noted correspondence, dated 20 February 2019, from the President of New Zealand Society for the Study of Diabetes (NZSSD), Dr Brandon Orr-Walker, on behalf of the NZSSD Executive regarding the funding of diabetes therapeutics in New Zealand.
- 1.2. Several members noted that they were members of NZSSD. Helen Lunt noted that while she was a member of the NZSSD, she had not had input into the 20 February 2019 letter.
- 1.3. The Subcommittee noted the key issues raised appeared to be primarily regarding the availability of funded therapeutic agents and devices for the treatment of diabetes, PHARMAC assessment processes, and the need for improved and meaningful engagement with clinicians who treat diabetes.
- 1.4. The Subcommittee noted that under the Subcommittee's Terms of Reference its role was to consider, report, or make recommendations and provide advice, on funding applications and proposals related to the management of the Pharmaceutical Schedule related to specific clinical therapy areas, in this case diabetes, or any other matters referred to it by PHARMAC.
- 1.5. The Subcommittee considered that, given its Terms of Reference, the issues and commentary regarding PHARMAC policy and process would be better addressed by PHARMAC staff. The Subcommittee noted that a formal response from PHARMAC would be prepared following the meeting.
- 1.6. The Subcommittee agreed that there was a disparity between the access to funded classes of diabetes medicines in New Zealand as compared to other jurisdictions such as Australia and the United Kingdom. The Subcommittee considered that for this reason international guidelines for the treatment of diabetes were not applicable to New Zealand. The Subcommittee considered that there were no current New Zealand-specific diabetes treatment guidelines or a mandated national group available to produce NZ guidelines that reflected current availability of funded medicines, placed within the context of the evidence base for diabetes management.
- 1.7. The Subcommittee noted that while access to pharmaceuticals was an important aspect for the appropriate management of diabetes, the relative influence pharmaceuticals provided in improving disease control in type 2 diabetes as compared to other interventions, such as structured exercise and dietary modification programs, should be acknowledged.
- 1.8. The Subcommittee considered that while it had been some time since the Subcommittee had last met in 2016, additional evidence published to support the use of diabetes agents has been considered by PTAC and is on the agenda for consideration by the Subcommittee at this meeting.
- 1.9. The Subcommittee considered that with respect to the funding of vildagliptin, Medsafe is the relevant body in New Zealand responsible for the regulation of medicines and medical devices in New Zealand and undertakes assessment of products to ensure that medicines and medical devices are acceptably safe.

- 1.10. The Subcommittee considered that in the absence of New Zealand appropriate treatment guidelines, BPAC articles were often referred to for guidance on appropriate prescribing practice. The Subcommittee noted that BPAC had published an article regarding the prescribing of vildagliptin alongside its listing, however considered there would be value in updating this information particularly with respect to guidelines for when to undertake liver function tests for patients taking vildagliptin.
- 1.11. The Subcommittee considered that it was important for PHARMAC to engage with diabetes clinicians to help improve the sector's understanding of, and to seek feedback on, its policy and processes.
- 1.12. The Subcommittee noted that some diabetes stakeholders currently receive emails regarding PHARMAC consultations, notifications and clinical advice records. The Subcommittee considered that accessibility could be improved by provision of plain language summaries of clinical advice and recommendations. The Subcommittee considered that additional engagement around implementation activities would be of value particularly when funding of new classes of treatment were proposed.

### *Insulin Priming*

- 1.13. The Subcommittee noted that PHARMAC has recently received correspondence from pharmacists and clinicians regarding the funding of priming for insulin, both for needles in the context of multiple daily injection (MDI) and for infusion sets in the context of insulin pumps.
- 1.14. The Subcommittee considered that priming the needle with at least 2 units prior to each injection is recommended and taught as standard best practice in New Zealand for patients on a MDI regimen. The Subcommittee noted this was regardless of whether the needle was changed on the pen device or not. The Subcommittee considered that priming was recommended as best practice both for insulin needles and for pump lines.
- 1.15. The Subcommittee considered that this correspondence indicated there appeared to be confusion in the sector regarding the funding of insulin for priming needles.
- 1.16. The Subcommittee also noted that the Schedule rules state in relation to claiming subsidies for funded medications 'Only a quantity sufficient to provide treatment for a period of up to 3 Months will be Subsidised'. The Subcommittee considered there was likely different interpretations in this setting as to whether a sufficient quantity included or excluded the amount required for priming.
- 1.17. The Subcommittee noted that the PHARMAC website provides guidance for pharmacists regarding insulin priming and what can be claimed for reimbursement. The Subcommittee noted the website states that 'the priming quantity is not funded. The number of vials is calculated on the doses required over three months'.
- 1.18. The Subcommittee also noted that insulin priming was considered by the Subcommittee at its last meeting held on 1 October 2016, at which it was considered the statement on the PHARMAC website that 'priming quantity was not funded' was incorrect as the amount of insulin that is prescribed by health professionals, which includes both therapeutic dose and priming dose of insulin, would be funded.
- 1.19. The Subcommittee considered there was a variation in prescriber practice currently with regards to insulin priming. The Subcommittee considered that the volume

required for priming was either added to the dose prescribed or specified separately on the prescription.

- 1.20. The Subcommittee noted that when the priming volume was added to the dose in some cases the dosage instructions on the prescription are intentionally vague or even incorrect to allow the extra priming quantity to be dispensed, which could present patient safety issues around the correct dose to administer. The Subcommittee also considered that as a result prescribing data for insulin dosing would be incorrect.
- 1.21. The Subcommittee noted that where priming was not included in the amount dispensed this would often mean that patients did not have sufficient insulin for a full 3 months' of treatment; meaning they returned earlier for another prescription and incurred the additional costs associated with this.
- 1.22. The Subcommittee considered that, regardless of prescriber approach, insulin priming for all patients was already included in current insulin expenditure so any change to prescribing or dispensing to make this explicit would not result in increased expenditure, however would reduce the impact on patients and improve the accuracy of data collection.

#### *Insulin glargine long-acting (brand name Toujeo)*

- 1.23. The Subcommittee noted that advice was sought from the Subcommittee regarding the funding of long-acting insulin glargine (brand name Toujeo) following PTAC's consideration of the application in February 2018.
- 1.24. The Subcommittee noted that long-acting insulin glargine (Toujeo) is a higher concentration formulation ie 300 units per ml, compared to standard insulin glargine (Lantus) which is 100 units per ml.
- 1.25. The Subcommittee noted that, in February 2018, PTAC had recommended that long-acting insulin glargine be funded for the treatment of type 1 and 2 diabetes only if cost neutral to the health sector.
- 1.26. The Subcommittee noted that PTAC also recommended that advice be specifically sought from the Diabetes Subcommittee regarding appropriate wording for funding restrictions that would target a high need groups who would derive the greatest clinical benefit from funded access to long-acting insulin glargine, if cost-neutrality could not be achieved.
- 1.27. The Subcommittee noted that biosimilar insulin glargine products that would provide competition for standard insulin glargine (Lantus) were coming to market internationally and so were likely to be available in the New Zealand market in the near future. The Subcommittee noted that any changes in the pricing of standard insulin glargine (Lantus) would affect the analysis of what price point would represent cost-neutrality for long-acting insulin glargine.
- 1.28. The Subcommittee considered that the currently available evidence for long-acting insulin glargine demonstrate that a similar level of clinical benefit as standard insulin glargine (Lantus) in the treatment of type 1 and type 2 diabetes, but with lower rates of hypoglycaemic events in type 2 diabetes patients previously receiving basal-bolus insulin. The Subcommittee noted that PTAC considered the reduction in the risks of hypoglycaemia was small and uncertain, and that additional patient monitoring was likely necessary.

- 1.29. The Subcommittee noted that a higher number of units per dose of long-acting insulin glargine was needed to achieve a similar level of glucose control as standard insulin glargine (Lantus).
- 1.30. The Subcommittee considered that if both standard insulin glargine (Lantus) and a long-acting form were available, as these were two different concentrations, this may introduce a small risk of error in hospitals where insulin was sometimes drawn up into syringes prior to administration.
- 1.31. The Subcommittee noted that the supplier had proposed long-acting insulin glargine could be targeted to patients who would most benefit and defined them as patients on standard insulin glargine (Lantus) for more than 6 months and who are experiencing a documented nocturnal or severe hypoglycaemic event; and patients who are injecting high volumes (over 80 units per day) of standard insulin glargine (Lantus).
- 1.32. The Subcommittee considered that it was not uncommon for patients to be using 80 units of standard insulin glargine (Lantus) per day and did not consider this to be an exceptionally high dose per day, particularly given delivery of large boluses was common practice.
- 1.33. The Subcommittee considered that HbA1c was often elevated in these patients, and the availability of long-acting glargine would not allow most of these patients to reach their HbA1c targets.
- 1.34. The Subcommittee considered that there was a preference for antidiabetic agents for the treatment of type 2 diabetes patients, however in the absence of funded access to these treatments a reduced volume insulin glargine option would be useful for this population.
- 1.35. The Subcommittee **recommended** that, if a cost-neutral listing without restrictions could not be achieved, then high need groups who would derive the greatest clinical benefit from funded long-acting insulin glargine could be targeted by application of the following Special Authority criteria:
  - Special Authority for Subsidy – Retail pharmacy
  - Initial application only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
  - All of the following:
    1. Patient has type 1 diabetes mellitus or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
    2. Patient has been treated with insulin glargine 100 units/mL for more than 6 months; and
    3. Any of the following
      - 3.1. Patient has experienced a documented and clinically relevant nocturnal or severe hypoglycaemic event while being treated with insulin glargine 100 units/mL; or
      - 3.2. Patient is regularly injecting greater than 150 units of insulin glargine 100 units/mL per dose.
  - Renewal application only from a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria:
    1. Patient is adherent to treatment regimen; and
    2. Patient is continuing to derive benefit according to treatment plan.
- 1.36. The Subcommittee noted that the availability of funded long-acting insulin glargine may provide additional flexibility around the timing of administration of insulin doses

by district nurses, however this was difficult to clinically define to target use in a Special Authority criteria.

- 1.37. The Subcommittee considered that long-acting insulin glargine provided the same or similar clinical benefit as insulin detemir, but was not therapeutically equivalent to insulin degludec based on a different duration of action.
- 1.38. The Subcommittee considered there could be a safety risk with different concentrations of glargine being available. The Subcommittee noted the supplier considered this risk was mitigated because the long-acting (high concentration) insulin glargine was not supplied in a vial presentation. The Subcommittee considered that a safety concern would still remain in the hospital setting where doses may be drawn up from a pen cartridge if clinical staff were not familiar with the use of a pen device, and that this would require education in hospital settings.
- 1.39. The Subcommittee noted that no other insulins listed on the Pharmaceutical Schedule currently have funding restrictions or Special Authority criteria applied. The Subcommittee noted that Lantus was previously subject to Special Authority criteria, but this was removed in 2010.
- 1.40. The Subcommittee considered that any funding decisions regarding long-acting insulin glargine should not impact on funded access to other funded diabetes treatments such as insulin pumps.

## **2. Therapeutic Group Review**

### *Insulin syringes and needles*

- 2.1. The Subcommittee noted a commercial proposal from a supplier requesting the listing of a range of BD Ultra-Fine insulin syringes with 6mm length needles attached. The Subcommittee considered there would be no change to insulin syringe usage volume if these additional syringes were listed on the Pharmaceutical Schedule as any uptake of a 6mm length needle syringe would displace usage of currently listed syringes with longer length needles. The Subcommittee considered there may be a suitability benefit of these devices over the currently listed products in children who had a preference for shorter needle lengths. The Subcommittee considered there may be a safety advantage over longer needle lengths for young children with limited sub-cutaneous fat in a reduced risk of intramuscular injection. The Subcommittee considered there would likely be significant usage in the hospital setting. The Subcommittee considered that any listing in either community or hospital should be at cost-neutral or better pricing to existing insulin syringe products.

### *Unifine Pentips Plus*

- 2.2. The Subcommittee noted an application from a supplier to fund Unifine Pentips Plus pen needles in New Zealand. The Subcommittee noted that the supplier indicates the needles are designed particularly for use by individuals with visual or dexterity impairments to increase needle exchange behaviour and to reduce the risk of needle stick injuries. The Subcommittee noted that the supplier had not provided any evidence to support these purported benefits.
- 2.3. The Subcommittee considered that insulin pen devices are not generally used in the hospital setting due to a risk of cross contamination of cartridges and therefore any use would likely be limited to community settings. The Subcommittee considered that pens would be used by patients living in managed care facilities

such as rest homes but that district health nurses would use syringes. The Subcommittee considered that the main use of this product would be by patients self-administering, and therefore at risk of self-stick injuries, and there were other ways to mitigate for the risk of needle stick injuries.

- 2.4. The Subcommittee considered that there did not appear to be a health need that is not already met by the currently listed pen needles and devices.
- 2.5. The Subcommittee considered that the use of Unifine Pentips Plus would increase plastic waste and the volume of pen needle utilisation compared with the currently listed devices. The Subcommittee considered that as with other needles Unifine Pentips Plus pen needles would also require disposal in a sharps container.
- 2.6. The Subcommittee **recommended** that Unifine Pentips Plus pen needles be funded only if cost neutral, and that cost neutrality should be established taking into account increased needle exchange behaviour and resultant increased needle utilisation.

#### *Insulin pumps and consumables*

- 2.7. The Subcommittee noted that the funded brands of insulin pumps listed in the Pharmaceutical Schedule changed from 1 November 2018. The Subcommittee noted that the currently listed pumps are Tandem (supplied by NZMS, formerly supplier of Animas Vibe) and MiniMed640G (supplied by Intermed on behalf of Medtronic, formerly supplier of Paradigm).
- 2.8. The Subcommittee noted that the change in funded brands of insulin pumps was in part due to a global discontinuation of the Animas Vibe pump and that as a result the supplier was transitioning all existing Animas users to the replacement Tandem t:slim X2 pump prior to 30 September 2019 in order to ensure it could fulfil its warranty requirements for these patients. The Subcommittee noted that the warranty period on replacement pumps will be valid for the same duration as the replaced Animas pump (ie if the Animas pump has 2 years remaining on its warranty then the replacement Tandem pump would have a 2-year warranty).
- 2.9. The Subcommittee considered that the ten-month transition period was insufficient given the number of patients that needed to be transitioned; but acknowledged that this transition period was unavoidable given the global discontinuation. The Subcommittee considered that ideally an eighteen-month transition period be allowed for with any future insulin pump brand changes of this nature.
- 2.10. The Subcommittee considered that the reason for the transition of patients with Animas pumps that were still 'in-warranty' could have been more clearly communicated to health care professionals and patients prior to the transition. The Subcommittee noted that many patients in this situation had a lack of choice in the short-term about the brand of pump they changed to but acknowledged that this had arisen due to the discontinuation and that the supplier was fulfilling its contractual requirements by providing replacements. The Subcommittee noted that Animas 'in warranty' patients (those whose Animas pump is less than 4 years old) would have a choice of the brand of funded pump at the end of the warranty period for their Animas pump, as the replacement Tandem pump has the same warranty end date.
- 2.11. The Subcommittee noted that PHARMAC was in close contact with the supplier and continue to actively monitor the implementation of this transition.
- 2.12. The Subcommittee considered that there was a Section 29 process in place for medicines when being prescribed outside the registered indications but there did



not appear to be a similar process in place for devices. The Subcommittee considered that the implications of an insulin pump device not being registered for children under the age of 6 were currently unclear, particularly with regards to the liability of prescribing in this age group, and that this raised a broader issue for PHARMAC when considering devices.

- 2.13. The Subcommittee noted that there are a number of insulin pumps emerging in the market, and that the technology is rapidly evolving. The Subcommittee considered that when reviewing such technologies, PHARMAC should consider how they are able to interface with interstitial glucose monitoring (either continuous or flash) technologies.
- 2.14. The Subcommittee considered that the provision of virtual pump applications available to health care professionals to facilitate upskilling and training is useful.
- 2.15. The Subcommittee considered that PHARMAC should take into consideration pump download software when making future funding decisions. The Subcommittee considered the ability for data to be downloaded from a pump was important for enhanced communication between patients and their healthcare team.
- 2.16. The Subcommittee considered that it would be beneficial to collect data on the rate of failure of insulin pump technology to provide information to patients regarding the type and frequency of failures which could be expected when using pump technology.
- 2.17. The Subcommittee noted a continued increase in utilisation of steel cannula insulin pump infusion sets. The Subcommittee considered this trend was likely due to patient preference for steel over teflon cannula devices. The Subcommittee considered this patient preference may be driven by better in-use life during exercise and sporting activities. The Subcommittee considered it was important to have a choice between steel and teflon cannulas, in particular for patients with skin allergies.
- 2.18. The Subcommittee noted the current Special Authority criteria for initiation and renewal of insulin pumps and consumables and considered these criteria should be reviewed in the near future with a view to equity and appropriateness of access to those patients that would benefit most from insulin pump therapy. The Subcommittee considered that clinical groups should be involved to seek views regarding any amendments to the funding of insulin pumps and consumables.

### **3. FreeStyle Libre Flash Glucose Monitoring system for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes**

#### *Application*

- 3.1. The Subcommittee reviewed an application from Abbott Laboratories NZ for the funding of the FreeStyle Libre Flash Glucose Monitoring system for the measurement of interstitial fluid glucose levels in individuals 4 years of age and over with type 1 diabetes.
- 3.2. The Subcommittee took into account, where applicable, PHARMAC's relevant decision-making framework when considering these agenda items.

#### *Recommendation*

- 3.3. The Subcommittee **recommended** that the FreeStyle Libre Flash Glucose Monitoring System be funded with **high** priority for certain patients with type 1 diabetes subject to the following Special Authority criteria:

Initial application – only from a relevant specialist or nurse practitioner. 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. Either:
  - 2.1. Patient is aged 18 years or under; or
  - 2.2. Patient is aged over 18 years; and
  - 2.3. Any of the following:
    - 2.3.1. Patient has impaired awareness of hypoglycaemia and has been admitted to hospital at least twice in the previous 12 months with hypoglycaemia requiring medical intervention; or
    - 2.3.2. Patient has been admitted to hospital at least twice in the previous 12 months with diabetic ketoacidosis; or
    - 2.3.3. Patient is pregnant, breastfeeding, or actively planning pregnancy.

Renewal application – only from a relevant specialist or nurse practitioner. Approvals valid for 24 months for applications meeting the following criteria:

1. Either:
  - 1.1. Both:
    - 1.1.1. Patient is continuing to derive benefit from flash glucose monitoring by achieving and maintaining a reduction of HbA1c from baseline of 10mmol/mol; and
    - 1.1.2. The number of hypoglycaemic episodes has not increased from baseline; or
  - 1.2. Both:
    - 1.2.1. Patient is continuing to derive benefit from flash glucose monitoring by achieving a 50% reduction from baseline in hypoglycaemic events; and
    - 1.2.2. HbA1c has not increased by more than 5mmol/mol from baseline.

#### *Discussion*

- 3.4. The Subcommittee noted a number of submissions from consumers and clinicians in support of funding for the FreeStyle Libre Flash Glucose Monitoring system.
- 3.5. The Subcommittee noted that type 1 diabetes is a chronic disease resulting from the autoimmune destruction of pancreatic  $\beta$ -cells resulting in insulin deficiency; and considered that there are likely to be approximately 25,000 individuals with type 1 diabetes in New Zealand.
- 3.6. The Subcommittee considered that while the prevalence of type 1 diabetes is higher in European/Pakeha than Māori and Pacific peoples, Māori and Pacific peoples have poorer long-term outcomes. Members considered that there was significant data regarding the inequities of outcomes for Māori and Pacific with type 2 diabetes and there was no reason to expect this would differ for type 1 patients.
- 3.7. The Subcommittee noted that individuals with type 1 diabetes use exogenous insulin to manage blood glucose levels but that maintaining a normal range can be difficult. The Subcommittee considered that to reduce the risk and avoid hypoglycaemia, patients often maintain their blood glucose levels in the mild-to-

moderate hyperglycaemic range, which can result in long-term microvascular and macrovascular damage.

- 3.8. The Subcommittee noted that type 1 diabetes can also have a negative impact on quality of life for affected individuals, particularly regarding physical functioning and wellbeing. The Subcommittee noted that the intensive management requirements, the fear of hypoglycaemia and hyperglycaemia, and the fear of long-term consequences, can result in significant stress and anxiety. The Subcommittee noted there is also a significant impact on the family and caregivers of individuals with type 1 diabetes.
- 3.9. The Subcommittee noted that the current standard of care for glucose monitoring in New Zealand is self-monitoring via a finger-prick blood test and patients are testing on average between four and ten times per day. The Subcommittee noted that diagnostic blood glucose test meters and consumables are funded for patients meeting certain eligibility criteria, including individuals receiving insulin.
- 3.10. The Subcommittee noted that the FreeStyle Libre is a Flash Glucose Monitoring (FGM) system that has three components: a disposable sensor, a reader, and optional software.
- 3.11. The Subcommittee noted that the sensor is applied usually to the upper arm using a disposable applicator, has a thin filament which is inserted under the skin, and that the sensor records data for up to 14 days with readings updated every minute and data stored every 15 minutes.
- 3.12. The Subcommittee noted that optional software allows monitoring of glucose using a smart phone, use of this software means that data is sent to a cloud-based server which can be accessed by the patient's healthcare professional. This data is also able to be accessed by the supplier.
- 3.13. The Subcommittee noted that the FreeStyle Libre has been registered on the Web Assisted Notification of Devices (WAND) database, which is a mandatory requirement for importers, exporters, and local manufacturers, and the sensor registration (15 January 2018; WAND reference: 180115-WAND-6PM9ZF) states the sensor is 'indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with insulin dependent diabetes mellitus. The indication for children (age 4 - 17) is limited to those who are supervised by a caregiver who is at least 18 years of age'.
- 3.14. The Subcommittee noted that the FreeStyle Libre does not require calibration, however patients would still be required to measure blood glucose via a finger-prick test during times of rapidly changing glucose levels or impending hypoglycaemia (approximately once every second day). The Subcommittee noted that the supplier indicates blood glucose levels as assessed by finger prick are better at informing treatment decisions in these situations. The Subcommittee noted that the FreeStyle reader could be used as a blood glucose meter; however only FreeStyle brand test strips could be used and these were no longer funded in New Zealand.
- 3.15. The Subcommittee noted that FreeStyle Libre FGM system differs from continuous glucose monitoring (CGM) systems primarily as it does not integrate with insulin pump devices, or provide continuous glucose monitoring, and does not have a hypoglycaemia alarm function which are features found in CGM technology.

- 3.16. The Subcommittee noted that the primary evidence for the use of FreeStyle Libre for the measurement of interstitial fluid glucose levels in individuals with type 1 diabetes is provided by the IMPACT trial ([Bolinder et al. Lancet. 2016;388:2254-2263](#)). The Subcommittee noted that IMPACT was a prospective, non-masked, randomised controlled trial which assessed whether FreeStyle Libre or self-monitored glucose testing reduced exposure to hypoglycaemia in 328 adults with well-controlled type 1 diabetes. The Subcommittee noted that the mean time spent in hypoglycaemia reduced by 1.39 hours per day in the FreeStyle Libre group compared with a reduction of 0.14 hours in the control group (between group difference -1.24; SE 0.239;  $P < 0.0001$ ). The Subcommittee noted that no device-related hypoglycaemia or safety concerns were reported. The Subcommittee noted that there was no significant difference in diabetes quality of life score between the groups (adjusted between-group difference -0.08; SE 0.039;  $P = 0.0524$ ).
- 3.17. The Subcommittee noted published correspondence to and from the authors of the IMPACT trial regarding concerns about skin adverse reactions ([Brahimi et al. Lancet 2017. 389:1396](#); [Bolinder et al. Lancet. 2017;389:1396-1397](#); [Aerts et al. Lancet. 2017;390:1644](#)). The Subcommittee considered that there would be a small proportion of patients who would experience adverse reactions to the adhesive used on the FreeStyle Libre sensor. The Subcommittee noted that there would also likely be incidents where the adhesive failed or the sensor was displaced, meaning that patients would require another sensor prior to the 14 day period was up and had the potential to be a fiscal risk. Members considered that the supplier appeared to be currently providing replacements sensors in the private market in these circumstances.
- 3.18. The Subcommittee noted that supporting evidence for the use of FreeStyle Libre in children and young adults is provided by the SELFY study, which was a single-arm, open-label study in 76 individuals aged 4 to 17 years with type 1 diabetes (Campbell et al. *Diabetologia*. 2017;60 [Suppl 1]:S1-S608 [conference abstract only]). The Subcommittee noted that the time in normoglycemic range (3.9 to 10.0 mmol/L) increased from baseline by a mean of  $1.0 \pm 2.8$  hours per day ( $P = 0.0056$ ), and that HbA1c reduced from baseline by  $-4.4 \pm 5.9$  mmol/mol ( $P < 0.0001$ ). The Subcommittee noted that three device-related adverse events were reported, and that there were no device-related serious adverse events.
- 3.19. The Subcommittee considered that there are a significant number of patients self-funding FreeStyle Libre in New Zealand and that this was resulting in further inequities in outcome for patients with type 1 diabetes.
- 3.20. The Subcommittee considered that the frequency with which patients with type 1 diabetes see health care providers is dependent on age and glycaemic control. If FreeStyle Libre were funded, the Subcommittee considered there may be some requirement for additional appointments with health care providers particularly initially and that the time required for patient management would be increased if data from the device were to be utilised. However, there may be a longer term reduction in management requirements if individuals improved glycaemic control and this could be significant if severe hypoglycaemic episodes and DKA were avoided.
- 3.21. The Subcommittee considered that access to a FGM system such as FreeStyle Libre for patients under the age of four could provide significant benefits but noted that there is currently no data available for this age group and it is outside the WAND registration.

- 3.22. The Subcommittee considered that if FreeStyle Libre were to be funded, that the uptake would be high, particularly for children and young adults. The Subcommittee considered that the main benefits of FGM appeared to be the convenience of testing, an increasing frequency of glucose testing and an associated flow on effect to improved glycaemic control. However, the Subcommittee considered this appeared to be a time bound effect in many patients.
- 3.23. The Subcommittee considered that for some patients who are not currently finger-prick testing for various reasons, having access to FGM technology could provide the data and motivation for improved glycaemic management.
- 3.24. The Subcommittee considered that approximately half of patients initially provided with FreeStyle Libre would continue using it long-term, either constantly or sporadically.
- 3.25. The Subcommittee considered that evidence for FGM was still developing and evolving but that this was a promising technology. The Subcommittee considered that the currently available evidence to support the efficacy and safety of FreeStyle Libre is of moderate quality.
- 3.26. The Subcommittee considered that funded access to an FGM system would benefit all patients with type 1 diabetes and as such there would likely be a significant fiscal impact associated with the funding of FreeStyle Libre. The Subcommittee considered that there are specific populations who have the highest health need for improved glycaemic control and who are likely to receive the most benefit from FreeStyle Libre and that it would be appropriate for funding to be initially targeted to these groups.
- 3.27. The Subcommittee considered that the highest priority for funding and patients most likely to benefit from FGM systems are children and young adults with type 1 diabetes. The Subcommittee considered other groups who could be targeted based on greater potential to benefit were patients with cystic fibrosis-related diabetes; patients with type 1 diabetes who are pregnant, breastfeeding, or actively planning pregnancy; patients with hypoglycaemia unawareness; and patients who have been admitted to hospital at least twice in the previous twelve months due to diabetic ketoacidosis or hypoglycaemia. The Subcommittee acknowledged that the population of people who would use FGM system during pregnancy, breastfeeding and those planning pregnancy would represent a very large number of patients and, as had been encountered with insulin pump funding, could be difficult to further define.
- 3.28. The Subcommittee noted that it would be important for ongoing funding criteria to require improvement in HbA1c and/or hypoglycaemic events to be demonstrated and that use should be discontinued where patients were not achieving an improvement in glycaemic control.

*General Comments regarding CGM and FGM*

- 3.29. The Subcommittee noted that there were several types of glucose monitoring technologies, currently available and under development, including continuous glucose monitoring (CGM) systems, flash glucose monitoring (FGM) systems, sensor- and flash-augmented pump therapy, hybrid closed-loop pump therapy, and fully closed loop therapy.
- 3.30. The Subcommittee considered that there were some major differences between CGM and FGM currently. Namely, CGM systems available at this time provide

continuous data, require 12-hourly blood glucose calibration, have alarms that can be set to detect out of range glucose levels, can be integrated with insulin pumps and some have predictive algorithms to suspend and resume insulin delivery; FGM systems while they do provide glucose level trend arrows to encourage closer monitoring or intervention and are factory calibrated, they currently require the sensor to be manually scanned and are not designed to be integrated with insulin pumps or provide alarm features for predicted hypoglycaemia.

- 3.31. The Subcommittee noted that some patients are using open-source transmitter attachments available on the market for use with FGM systems that allow for continuous glucose readings and alarm functionality (e.g. the MIAOMIAO Smart Reader).
- 3.32. The Subcommittee considered that this raised several areas of concern that were broader issues for PHARMAC with the use of community devices, particularly given the limited regulatory controls around devices products in New Zealand currently. Members considered that safety for diabetes patients using devices was a significant concern especially where closed loop systems were being used. Members considered that it was unclear whether support from suppliers would be provided for patients using open-source or other “DIY” technology who ran into technical issues, had device failure or experienced adverse events.
- 3.33. The Subcommittee considered that the use of devices in this way also raised a number of data governance and privacy considerations including: who owned the data generated; how it was shared, accessed and interpreted; appropriately gained consent for its use; and the training and resourcing of health professionals to manage this.
- 3.34. The Subcommittee considered that the field of glucose monitoring technologies is developing rapidly, in regard to both hardware and software. The Subcommittee considered that as the technology develops additional features will likely include improved sensitivity, reduced requirement for calibration, and closed-loop functionality.
- 3.35. The Subcommittee considered that that given the interlinked nature of insulin pump and CGM technology, any future decisions to fund these devices in the New Zealand market should consider how these technologies integrate with each other. The Subcommittee considered there would be a preference for pump ‘agnostic’ interstitial glucose monitoring technology.
- 3.36. The Subcommittee considered that the fast moving pace of technology development in the devices field, and the complexity of the devices themselves, meant that consideration needed to be given to the availability of appropriate systems and services so that patients and healthcare professionals were adequately supported to use these products. The Subcommittee considered it was particularly important that accurate, reliable and useful information could be accessed easily to troubleshoot any issues that arose.
- 3.37. The Subcommittee considered that the introduction of any CGM or FGM technology would impart a significant burden on health care system due to the resources required to adequately train and educate healthcare professionals, patients, and caregivers on the use of the devices. The Subcommittee considered that the volume of information provided by these technologies would be clinically beneficial but would likely significantly increase the time required for health care professionals to incorporate this into their clinical decision-making.

- 3.38. The Subcommittee considered that it will be critical that appropriate education be provided to health care professionals for any CGM or FGM technology introduced to New Zealand. The Subcommittee considered that it would be important that this is product specific, but also that there is a centrally collated information source with resources available regarding all products and technologies that patients may be using and practical details guiding where further information can be found, and how and where to get replacement products.
- 3.39. The Subcommittee considered it would likely be important for the contractual requirements for suppliers address issues specific to devices such as training, support, data governance as well as terms for discontinuation scenarios and replacement of devices.
- 3.40. The Subcommittee considered that the quality of evidence available regarding the efficacy and safety of CGM and FGM technologies is affected by the inability to conduct blinded randomised controlled trials, as the intent of the devices is that blood glucose monitoring is visible (in other words, it is not possible to use a 'sham' device in an randomised controlled trial setting). The Subcommittee considered that much of the data currently available was based on relatively short follow up of 3-6 months for what was a long-term disease and that data with longer timeframes would be of more interest.
- 3.41. The Subcommittee considered that future review of CGM and FGM funding applications will require data indicating the impact of the technology on blood glucose time in range and haemoglobin A1c (HbA1c) levels, utility in broader patient groups, and long-term efficacy and safety data. The Subcommittee considered that it was likely for diabetes patients using CGM technology they would reduce the volume of blood glucose test strips.
- 3.42. Members considered that the impact of this technology was more complex than just changes in HbA1c as it would also provide convenience that would impact on a diabetic patients' lifestyle and reduce stress associated with managing their condition; and that there may be challenges for translating these kinds of benefits in a health technology assessment.
- 3.43. The Subcommittee considered that real-world analyses may provide the most valuable data for glucose monitoring technologies. Members noted that evaluation of CGM in Australia was currently underway and that analysis of 12 month data would likely be available soon. Members considered the 6 month data indicated a reduction in hypoglycaemic events and a mild benefit in terms of HbA1c from use of CGM.
- 3.44. The Subcommittee considered that further data was needed to help inform which populations gained benefit from use of CGM. The Subcommittee considered that the data required would likely need to come from rich and diverse sources and was likely to be different from that traditionally provided to support medicines funding.
- 3.45. The Subcommittee considered that glucose monitoring systems such as CGM and FGM are likely to provide significant benefit to certain patients who are receptive and responsive to the technology, but that it will be difficult to prospectively identify who these individuals will be. Members considered that based on observations in the private market there were clearly some patients who benefitted and others who did not however, any access criteria needed to be carefully considered so that disparities would not be exacerbated.

## 4. Anti-diabetic agents for the treatment of type 2 diabetes

### *Application*

- 4.1. The Subcommittee noted advice was sought regarding the diabetes treatment paradigm; class effects for antidiabetic agents in light of recently published data for cardiovascular and/or renal outcomes in T2DM patients; and appropriate access criteria for antidiabetic agents, including definition of a high cardiovascular risk population.
- 4.2. The Subcommittee took into account, where applicable, PHARMAC's relevant decision-making framework when considering these agenda items.

### *Recommendation*

- 4.3. The Subcommittee recommended that antidiabetic agents be funded for the improvement of cardiovascular outcomes in T2DM patients with established CVD subject to the following Special Authority criteria:

Initial application from any medical practitioner. Approvals valid without renewal for applications meeting the following criteria:

All of the following:

1. Patient has type 2 diabetes; and
  2. Patient has not achieved target HbA1c (of less than 64mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months; and
  3. Patient has 5 year absolute cardiovascular disease risk of 20% or greater according to a validated diabetes cardiovascular risk assessment calculator; and
  4. Treatment is used to be used in conjunction with other measures to reduce cardiovascular risk in line with current standard of care; and
  5. Treatment must be used as adjunct to oral antidiabetic therapy and/or insulin.
- 4.4. The Subcommittee recommended that the percentage risk threshold in the recommended criteria could be lowered to also include funding for T2DM patients with high cardiovascular risk.

### *Discussion*

- 4.5. The Subcommittee noted the high health need of T2DM in New Zealand and the disproportionately higher disease burden that occurs in Māori, Pacific and South East Asian population where the disease is more prevalent, and its generally earlier onset in these populations means T2DM and its associated comorbidities are experienced at a younger age.
- 4.6. The Subcommittee noted that the funding of antidiabetic agents has been previously considered by PTAC and the Diabetes Subcommittee individually and together on a number of occasions; and that the outcome of these previous reviews was that overall it had been considered these agents had a similar effect of reducing HbA1c by 5-10 mmol/mol (0.5% to 1%) when added to metformin.
- 4.7. The Subcommittee noted that more recently long term follow up data for cardiovascular and renal outcomes for several antidiabetic agents had been published.
- 4.8. The Subcommittee noted that at its meeting in February 2019 PTAC had again reviewed the funding of antidiabetic agents for the treatment of T2DM and had considered the available published data for cardiovascular risks and benefits of DPP4 inhibitors, glucagon-like peptide-1 (GLP-1) receptor agonists, and sodium-



glucose cotransporter 2 (SGLT2) inhibitors in the treatment of T2DM and whether this data indicated a class effect.

- 4.9. The Subcommittee noted that PTAC had recommended advice be sought from the Diabetes Subcommittee regarding the appropriate place for SGLT2 inhibitors and GLP-1 receptor agonists in the New Zealand treatment paradigm, further consideration of class effect with these agents including the impact of trial population heterogeneity on reported outcomes, and appropriate access criteria including definition of high risk cardiovascular populations.
- 4.10. The Subcommittee noted the published evidence for cardiovascular outcome trials for the SGLT2 inhibitors and GLP-1 receptor agonists including:
- Canagliflozin: CANVAS and CANVAS R [Neal et al, N Engl J Med. 2017;377:644-57](#)
  - Dapagliflozin: DECLARE-TIMI 58 – [Wiviott et al, N Engl J Med. 2019;380:347-57](#)
  - Empagliflozin: EMPA-REG outcome – [Zinman et al, N Engl J Med. 2015;373:2117-28](#)
  - Liraglutide: LEADER trial – [Maso et al, N Engl J Med. 2016;375:311-22.](#)
  - Semaglutide: SUSTAIN 6 – [Maso et al, N Engl J Med. 2016;375:1834-44](#)
  - Exenatide: EXSCEL – [Holman et al, N Engl J Med. 2017;377:1228-39.](#)
  - Albiglutide: HARMONY – [Hernandez et al, Lancet. 2018;392:1519-29.](#)
- 4.11. The Subcommittee noted that the aim of these cardiovascular outcome trials was to demonstrate that these agents were at least non-inferior to current therapies with respect to macrovascular outcomes.
- 4.12. The Subcommittee also noted additional published evidence from a variety of other publications including real-world observational studies, systematic reviews and meta-analysis including Storgaard et al. PLoS One. 2016;11:e0166125; Zelniker TA et al. Lancet 2019;393:31-9; Kosiborod et al. Diabetes Obes Metab. 2018;20:1983-7; Norhammar A, et al Diabetes Obes Metab. 2019 doi: 10.1111; Home et al, Diabetologia. 2019; 62:357-69; Fei et al, Int J Cardiol. 2018;254:291-6; Muskiet et al, Lancet Diabetes Endocrinol. 2018;6:674-6.
- 4.13. The Subcommittee considered that both the clinical trial and real-world observational evidence of cardiovascular and renal outcomes of antidiabetic agents is continuing to evolve and develop; noting that a large number of studies are ongoing and likely to publish further data in the next two years that would help with refining the appropriate placement of these agents in the treatment paradigm.

#### *Diabetes Treatment Paradigm*

- 4.14. The Subcommittee considered that current practice for diabetes treatment in New Zealand reflects the Ministry of Health Diabetes Guidelines published in 2011. The Subcommittee considered that these Guidelines are not up to date and that it would be valuable to the diabetes health workforce for these to be revised to include guidance on the use of antidiabetic agents in light of more recently published evidence.
- 4.15. The Subcommittee noted several international [guidelines](#) including the NICE guidance document for T2DM in adults management published in 2015 and the joint

consensus report for the management of hyperglycaemia in T2DM published in 2018 by the American Diabetes Association (ADA) and the European Association for the study of diabetes (EASD) ([Davies et al, Diabetes Care. 2018;41:2669-701](#)). The Subcommittee noted that the ADA and EASD consensus report makes the following recommendations:

- 1) T2DM with established cardiovascular disease would benefit from either a SGLT-2 inhibitor or GLP-1 receptor agonist with proven cardiovascular benefit.
  - 2) T2DM with established cardiovascular disease and a high risk of heart failure would benefit from a SGLT-2 inhibitor
  - 3) T2DM with chronic kidney disease irrespective of cardiovascular disease risk would benefit from a SGLT-2 inhibitor shown to reduce chronic kidney disease progression. If an SGLT-2 inhibitor is contraindicated or not preferred a GLP-1 receptor agonist shown to reduce chronic kidney disease progression would be recommended.
- 4.16. The Subcommittee considered that if any additional antidiabetic agents were to be listed, they would be used as an add-on to current therapy with metformin and/or sulphonylurea, ultimately providing an additional line of therapy prior to progression to insulin. The Subcommittee considered that upon progression to insulin use of the anti-diabetic agents was unlikely to be ceased.
- 4.17. The Subcommittee further considered that one agent from each class of anti-diabetic agents would be prescribed to an individual if it aligned with New Zealand guideline recommendations and was permitted under funding criteria. The Subcommittee considered that funding criteria would need to be applied if restriction of populations and prescribing of these agents was necessary for fiscal reasons.

#### *Consideration of class effects*

- 4.18. The Subcommittee considered that based on the currently available literature the DPP-4 inhibitors as a class have similar glucose lowering therapeutic effects but the effect of the class on cardiovascular outcomes is neither inferior or superior to current treatment.
- 4.19. The Subcommittee considered that current uptake of the listed DPP-4 inhibitor, vildagliptin, did not reflect the total market size for this class of agents and were another DPP4 agent listed there would likely be an increase in the total number of patients prescribed a DPP4 inhibitor.
- 4.20. The Subcommittee considered that cardiovascular outcome data for GLP-1 receptor agonists available to date shows a consistent signal for a reduction in all-cause mortality, cardiovascular mortality, and heart failure hospitalisation can be achieved with each GLP-1 receptor agonist agent within the class. The Subcommittee considered that this positive therapeutic effect from GLP-1 receptor agonists appears to occur irrespective of baseline cardiovascular or renal risk. The Subcommittee considered that in terms of cardiovascular outcomes GLP-1 agents provided the same or similar level of benefit for people with T2DM.
- 4.21. The Subcommittee noted that GLP-1 receptor agonists are an injection and considered that clinician and patient preference may be for the other classes of antidiabetic agents which are oral tablets.
- 4.22. The Subcommittee considered that current evidence for SGLT2 inhibitors suggests that there is likely a positive therapeutic benefit on the risk of heart failure hospitalisation and progression of renal composite outcomes with SGLT2 inhibitor

agents, with some SGLT2 inhibitors also demonstrating a positive effect on the risk of major adverse cardiovascular events (MACE), cardiovascular mortality and all-cause mortality. The Committee considers that for an established cardiovascular risk T2DM population the evidence clearly demonstrates a class effect in terms of cardiovascular outcomes and there is also a trend, although not as significant, that this is also the case for a high cardiovascular risk population without established disease.

- 4.23. The Subcommittee acknowledged there is currently a level of uncertainty due to the variation of cardiovascular disease and renal characteristics of participants in the trial populations but overall considered there is a similar therapeutic benefit in terms of cardiovascular outcomes within the SGLT2 inhibitor class. The Subcommittee noted that internationally this uncertainty is recognised in guidelines, however considered that as more evidence becomes available it is likely class effects will be clearly seen.
- 4.24. The Subcommittee considered that current evidence supports class effects with the classes of antidiabetic agents in terms of renal benefits for T2DM patients.
- 4.25. The Subcommittee considered that funding an agent from each of the SGLT2 inhibitor and GLP-1 receptor agonist classes would enable clinical decision making for the most appropriate therapy to address relative cardiovascular disease risk and health need of individual patients.
- 4.26. The Subcommittee considered that T2DM patients currently on insulin treatment would likely also commence on antidiabetic agents for the cardiovascular benefits, if funding arrangements allow this, and that this would likely mean a decrease in insulin resistance and therefore insulin requirements in these patients.

#### *Access criteria and high risk population definition*

- 4.27. The Subcommittee considered that the current data for improved cardiovascular outcomes from antidiabetic agents was strongest for established cardiovascular risk populations and those with renal disease. The Subcommittee considered that if for fiscal reasons funding were to be targeted to a certain T2DM subgroup this was the population best supported by the current evidence as likely to benefit the most from use of these agents. However, the Subcommittee considered that it would be more clinically appropriate to treat patients earlier rather than waiting for a cardiovascular event to occur.
- 4.28. The Subcommittee considered that 'established cardiovascular disease' was a generally well understood and clear definition, however there was inequity of access for diagnosis of cardiovascular disease for Maori and Pacific peoples and therefore considered that it would be more appropriate to use a 5-year cardiovascular disease (CVD) risk threshold as determined by using a validated diabetes risk calculated to help address this inequity rather than defining access based on a definition of 'established' disease.
- 4.29. The Committee considered that in a New Zealand clinical practice setting using the cardiovascular disease risk assessment tool for patients with T2DM in New Zealand provided by the New Zealand Society for the Study of Diabetes (NZSSD) would be an appropriate method of estimating a patient's 5-year absolute CVD risk or probability of having a CVD event in the next 5-years for a T2DM patient without established disease.

- 4.30. The Subcommittee noted that this rapid calculator is based on New Zealand specific data and research conducted by the University of Auckland and considers the following variables: age, duration of diabetes, gender, smoking status, systolic blood pressure, HbA1c, ethnicity, total cholesterol, high density lipoprotein (HDL), albuminuria and blood pressure medication status.
- 4.31. The Subcommittee considered that a minimum 5-year CVD risk of 15% according to the NZSSD tool would be considered high risk in New Zealand taking into account the disproportionate disease burden in Māori and Pacific populations. The Subcommittee considered that this threshold would be appropriate to encompass the characteristics of a high risk population when converting the characteristics of participants in the cardiovascular outcome clinical trials.
- 4.32. The Subcommittee noted that the NZSSD risk assessment tool may not be appropriate for use in T2DM patients who have had a CVD event (established CVD) but considered that for an established cardiovascular risk population, the occurrence of a CVD event in and of itself would result in a 5-year CVD risk of greater than 20%.

## **5. Glucose Solution (HypoPak) for the treatment of hypoglycaemia**

### *Application*

- 5.1. The Subcommittee reviewed an application for the funding of glucose solution plus complex carbohydrate, brand name HypoPak (15 g glucose sachet and a 20 g vanilla gluten, dairy, and egg free biscuit) for the treatment of hypoglycaemia.
- 5.2. The Subcommittee took into account, where applicable, PHARMAC's relevant decision-making framework when considering this agenda item.

### *Recommendation*

- 5.3. The Subcommittee recommended that glucose solution plus complex carbohydrate, brand name HypoPak (15 g glucose sachet and a 20 g vanilla gluten, dairy, and egg free biscuit) be funded only if cost-neutral to the glucose with sucrose and fructose gel, 18 g sachet currently listed on the Hospital Medicines List (HML).

### *Discussion*

- 5.4. The Subcommittee noted that each HypoPak consists of one sachet containing 15 g glucose in 80 mL of water and one 20 g biscuit that is gluten, egg, and dairy free, packaged together in a plastic pouch with a removable medical notes sticker and instructions for use. The Subcommittee noted that the 15 g glucose sachets can also be purchased as individual units.
- 5.5. The Subcommittee noted the shelf-life of HypoPak is two years and considered this to be relatively short as compared to currently listed products for the treatment of hypoglycaemia.
- 5.6. The Subcommittee noted that the funding application requested listing on the HML only as use of HypoPak would primarily be for the treatment of hypoglycaemia in a hospital setting.
- 5.7. The Subcommittee considered that hypoglycaemic episodes, defined by blood glucose levels below 4 mmol/L or where symptoms of hypoglycaemia are experienced with blood glucose levels close to 4 mmol/L, occur frequently in the hospital setting, particularly overnight.

- 5.8. The Subcommittee considered that initial treatment for conscious patients experiencing hypoglycaemia is to provide 15 g to 20 g of glucose orally. The Subcommittee considered that where patients are unconscious treatment is with intravenous dextrose or intramuscular glucagon hydrochloride.
- 5.9. The Subcommittee noted that there are a number of products already listed on the HML that can be used for the management of hypoglycaemia in patients who are conscious and able to swallow, including glucose tablets, glucose with sucrose and fructose gel 18 g sachet, and glucose powder.
- 5.10. The Subcommittee noted that once a patient experiencing a hypoglycaemic episode is provided with glucose and their serum blood glucose levels return to normal, best practice is for the consumption of a meal or snack to prevent hypoglycaemia recurring. The Subcommittee noted that currently, a patient would be provided with a sandwich, a milo, a biscuit, or another appropriate food item depending on what is available at the time.
- 5.11. The Subcommittee considered that it was likely that management protocols for treating hypoglycaemic episodes vary between District Health Boards (DHBs). The Subcommittee considered that hypoglycaemic episodes are well managed in some hospitals, but there may be some hospitals in which hypoglycaemia management could be more effective.
- 5.12. The Subcommittee considered that where improvements were required for in-hospital hypoglycaemic episode management, this could be addressed by changes in hospital systems and protocols while utilising the products currently listed on the HML. The Subcommittee considered that this could be achieved by the production of standardised guidelines for hypoglycaemic management across DHBs.
- 5.13. The Subcommittee noted that some DHBs were currently pre-preparing glucose solution products from HML listed products in the hospital pharmacy for use on wards. The Subcommittee considered that access to HypoPak may reduce the time spent preparing these products in the pharmacy in these DHBs, however considered that at the pricing currently proposed by the supplier, Hypopak would likely result in additional costs to DHBs even taking into account this offset and uncertainty regarding currently uncontracted HML listed products. The Subcommittee also considered that HypoPak may present issues for current pharmacy storage systems.
- 5.14. The Subcommittee considered that it is not aware of any evidence to suggest there is an unmet health need for alternative products for managing hypoglycaemic episodes within the hospital setting.
- 5.15. The Subcommittee noted a number of published articles for the health benefits provided by ingestion of a rapidly absorbed carbohydrate followed by a meal or a snack for the treatment of hypoglycaemic episodes provided by the applicant in support of the submission.
- 5.16. The Subcommittee considered that there is a lack of evidence demonstrating that access to HypoPak would improve the management and health outcomes of patients experiencing hypoglycaemia compared with currently listed options.
- 5.17. Given the lack of a demonstrated health need or evidence to support improved outcomes as a result of the use of Hypopak, the Subcommittee considered that there was no justification for a listing at a higher price point than currently listed

products for the treatment of hypoglycaemia. The Subcommittee considered that funding should be progressed only if cost-neutral to products for the treatment of hypoglycaemia currently listed on the HML; and considered it most appropriate to assess cost-neutrality as compared to glucose with sucrose and fructose gel, 18 g sachet.