Record of the Diabetes Advisory Committee Meeting held on 21 June 2024 via Zoom

Diabetes Advisory Committee records are published in accordance with the Terms of Reference for the Specialist Advisory Committees 2021.

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

The Diabetes Advisory Committee 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.

Pharmac Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Committee meeting was reviewed by PTAC at its August 2024 meeting.

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of anyone funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

Contents

1. Attendance

Present
Chair – Bruce King
Helen Lunt
Rinki Murphy
Esko Wiltshire
Diana McNeill
Kate Smallman
Karen MacKenzie

Apologies
Elizabeth Dennett
Nic Crook
Angela Renall
Sean Hanna

2. The role of Specialist Advisory Committees and records of meetings

2.1. This meeting record of the Diabetes Advisory Committee is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 2021 and Specialist Advisory Committees 2021.Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.

2.2. Conflicts of Interest are described and managed in accordance with section 6.4 of the SAC Terms of Reference.

2.3. The Diabetes Advisory Committee is a Specialist Advisory Committee of Pharmac. The Diabetes Advisory Committee and PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Diabetes Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for treatments for mental health that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for mental health that differ from the Diabetes Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by both the Diabetes Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for treatments for mental health.

3. Welcome and introduction

3.1. The meeting commenced with an opening karakia.

3.2. The Committee noted the purpose of the meeting is to consider some clinical aspects of the proposal to fund Insulin Pumps and consumables and Continuous Glucose Monitors (CGMs) and associated Automatic Insulin Delivery (AID) system capability that arose from the feedback received during the public consultation, as well as some new information gathered since the close of consultation.

4. Transition and Implementation Considerations

Recommendation

4.1. The Committee **recommended** extending the proposed transition period for insulin pumps and consumables to 24 months, as this was necessary to enable sufficient time for people with diabetes and the clinical teams supporting them, to complete the transition to a new system, due to the resource constraints in the health system.

Discussion

4.2. The Committee noted the feedback received regarding resource constraints in the public health sector which could pose challenges to achieving a successful transition for those individuals currently using a funded MiniMed 770G insulin pump within the proposed 12-month transition timeframe.

4.3. The Committee noted specific concerns expressed in relation to resource constraints in the public health sector, and the inability of some regions in particular to manage a transition onto the proposed insulin pumps in the timeframes suggested.

4.4. The Committee noted that some regions in the country such as Canterbury and Southern had a much higher proportion of individuals currently using the Medtronic insulin pump as opposed to the Tandem pump. The Committee considered that these regions would be required to transition more individuals onto the proposed pumps, as well as maintain onboarding new people onto insulin pump therapy.

4.5. The Committee acknowledged that grandparenting those people who are currently receiving a Medtronic supplied pump would not be possible within the current commercial parameters. The Committee considered that a period of 24 months would allow sufficient time to transition individuals currently receiving a Medtronic supplied pump to one of the proposed funded options. The Committee considered that an extension from 12 to 24 months was particularly necessary in those regions with a high proportion of Medtronic pump users, and those with a significant number of young Medtronic pump users.

4.6. The Committee considered whether it would be appropriate to provide Pharmac funding for a Medtronic AID compatible CGM during the proposed transition period to ensure equitable access to a funded AID system for current Medtronic pump users. The Committee noted however that there was continued funding support available for these people through other government agencies to enable funding of a CGM. The Committee noted that diabetes services would be prioritising the transition of existing pump users to minimise any access inequities.

5. Renewal criteria for Continuous Glucose Monitors

Recommendation

5.1. The Committee **recommended** that the criteria for ascertaining renewal eligibility be **amended** as follows and that renewal should be approved if treating clinicians could confirm that in their opinion the individual was still deriving a health benefit.

Renewal – (type 1 diabetes) from any relevant practitioner. 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.
2. ~~There is objective evidence of maintained improvement in glycaemic control~~.

Discussion

5.2. The Committee noted the feedback received requesting that the requirement to demonstrate that *"There is objective evidence of maintained improvement in glycaemic control"* be removed from the criteria for Continuous Glucose Monitors (CGM).

5.3. The Committee noted that the proposed renewal criteria for CGM's included the requirement to show evidence of an improvement in glycaemic control following the initiation of CGM usage. The Committee considered that it was not necessarily clinically appropriate to focus so strongly on glycaemic control as a basis for renewal, and that individuals would derive clinically meaningful health benefit beyond demonstrating an improvement in glycaemic control. This benefit would include aspects such as greater time in range, reduced burden of finger prick testing and a reduction in psychological distress due to potential hypoglycaemic events.

5.4. The Committee noted that a significant health benefit of CGM's was a reduction in "diabetes fatigue" which was a more subjective measure of health gain, and that this equated to a meaningful gain in quality of life for the individual and is of great value.

5.5. The Committee considered that it was unlikely that treating clinicians would seek a renewal for CGM funding for an individual who was no longer deriving a health benefit from access to the technology, and that removing the requirement for objective improvement in glycaemic control would be unlikely to have an impact on the number of people maintaining funded access to CGM's. In addition, the Committee considered that this would reduce inequities that may arise through inconsistent interpretation of the renewal criteria.

6. Consideration of Additional Populations for CGM funding

Recommendation

6.1. The Committee **recommended** that the proposed eligibility criteria for Dexcom One Plus and Freestyle Libre 2 be **amended** from the criteria consulted on as follows: (additions in bold and deletions in strikethrough)

Initial application (type 1 diabetes) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria
Any of the following:
1. The patient has type 1 **diabetes** ~~or pancreatogenic* diabetes~~; or
2. **The patient has permanent neonatal diabetes or specific mongenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist as likely to benefit.**
3. **The patient has Type 3c diabetes considered by the treating endocrinologist as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis); or**
4. **The patient has an atypical inherited form of diabetes.**

~~*This includes permanent neonatal diabetes or patients with insulin deficiency secondary to cystic -fibrosis or pancreatectomy~~

6.2. The Committee **recommended** that the proposed eligibility criteria for either Dexcom G6 / G7 or an Abbott branded AID compatible CGM be **amended** from the criteria consulted on as follows:

Initial application (type 1 diabetes) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria
Both:

~~1. Patient has type 1 or pancratogenic * diabetes; and~~

1. Any of the following:
   - **1.1. The patient has type 1 diabetes; or**
   - **1.2. The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist as likely to benefit; or**
   - **1.3. The patient has Type 3c diabetes considered by the treating endocrinologist as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis).; or**
   - **The patient has atypical inherited forms of diabetes; and**
2. **In the opinion of the treating relevant practitioner the patient would benefit from an Automated Insulin Delivery (AID) system**

~~*This includes permanent neonatal diabetes or patients with insulin deficiency secondary to cystic -fibrosis or pancreatectomy~~

Discussion

6.3. The Committee noted that consultation feedback had been received requesting access for additional defined populations with diabetes. The Committee noted that the feedback received reflected uncertainty regarding those who would, or would not, be eligible for funded CGM's based on the proposed eligibility criteria, or the requested wider access to CGM's to include specific groups of individuals. The Committee considered that the intent of this funding proposal was for individuals with type 1 diabetes and noted that insulin pumps and CGM's for those with insulin dependent type 2 diabetes mellitus (T2DM) would be considered at a future date.

Latent Autoimmune Diabetes in Adults (LADA)

6.4. The Committee noted that population with LADA would be inherently included in the proposed current eligibility criteria as a form of type 1 diabetes and would therefore meet the intent of the current criteria without the need to amend the criteria explicitly.

Gestational Diabetes

6.5. The Committee considered whether people with gestational diabetes should be included in the eligible population in the current proposal for the funding of CGM's and insulin pumps for people with Type 1 diabetes.

6.6. The Committee considered that the health need for individuals with gestational diabetes was in general appreciably less than for the target population of people living with Type 1 diabetes being considered in the proposal and should be considered as a separate population for funding.

6.7. The Committee considered that the health need of people with gestational diabetes was different than people whose pregnancy was complicated by T2DM and were insulin requiring, as they were generally at less risk of significant hypoglycaemic events. The Committee noted that in some regions the number of pregnant people with T2DM requiring insulin is substantial.

6.8. The Committee considered that while there was an unmet health need for pregnant people with T2DM requiring insulin. The Committee recommended that this group should be considered as part of a funding application for people with T2DM, rather than the current funding proposal under consideration. The Committee supported an application for this group either specifically or as part of a wider application that included additional T2DM populations and that this should be developed as a priority.

Monogenic Diabetes

6.9. The Committee considered that Mature Onset Diabetes of the Young (MODY) was a genetic atypical form of diabetes and was referred to as monogenic diabetes. The Committee considered that not all forms of monogenic diabetes would require treatment, and that treatment decisions should be made by an endocrinologist.

6.10. The Committee considered that diabetes due to Wolfram Syndrome would also be most appropriately considered as a form under the general category of monogenic diabetes, as a syndromic subtype

6.11. The Committee considered that it would be appropriate to include people with forms of monogenic diabetes where the condition was symptomatic and required treatment.

6.12. The Committee considered that it would be reasonable to extend access to those people with certain forms of atypical genetic diabetes, such as those suffering from mitochondrial diabetes, poor functioning of insulin-producing cells in the pancreas and/or the emergence of insulin resistance as part of a mitochondrial disorder.

Post transplant diabetes

6.13. The Committee considered that people who present with diabetes in a post-transplant setting have a similar health need to those with T2DM. The Committee considered that Post transplant diabetes is best considered as a form of non-type 1 diabetes, with similarities to type 2 diabetes and thus would not be included as part of the population under consideration in the current proposal. However, the Committee considered that the unmet health need would be similar to a larger group of people with T2DM and should be considered alongside any the consideration of a proposal to fund access to CGM's for people with T2DM.

Pancreatic Insufficiency

6.14. The Committee noted the high health need of people with diabetes related to exocrine and endocrine pancreatic insufficiency from conditions such as chronic pancreatitis. The Committee considered that for people with pancreatic insufficiency where there is a requirement for insulin therapy would likely have a health need similar to those with type 1 diabetes.

6.15. The Committee considered that it would be appropriate to include people with pancreatic insufficiency as part of the population being considered for funding in the proposal. The Committee considered that there is variability in the interpretation of the current insulin pump criteria and its reference to pancreatectomy.

6.16. The Committee considered that amendments to the eligibility criteria to explicitly include this population would improve equity of access. The Committee considered that this group of people with exocrine and endocrine pancreatic insufficiency would be relatively small, and mainly in the adult population.

7. Proposed Special Authority Criteria – Insulin Pumps

Recommendation

7.1. The Committee **recommended** several **amendments** to the proposed eligibility criteria for insulin pumps as follows: (additions in bold and deletions in strikethrough)

Special Authority for Subsidy
Initial applications – (type 1 diabetes) from any relevant practitioner. Approvals valid for ~~3~~**6** months for applications meeting the following criteria:
All of the following:

1. Any of the following:
   - **1.1. The patient has type 1 diabetes; or**
   - **1.2. The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist as likely to benefit; or**
   - **1.3. The patient has Type 3c diabetes considered by the treating endocrinologist as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis); or**
   - **1.4. The patient has atypical inherited forms of diabetes; and**
2. Patient has been evaluated by a diabetes multidisciplinary team for their suitability for insulin pump therapy; and ;

~~3. Either:~~
~~3.1.Both~~
~~3.1.1. Has adhered to an intensive MDI regime using analogue insulins for at least three months; and~~
~~3.1.2. Has any of the following;~~
~~3.1.2.1. Severe unexplained nocturnal hypoglycaemia; or~~
~~3.1.2.2. Severe unexplained hypoglycaemia requiring assistance; or~~
~~3.1.2.3. Chronically raised HbA1c despite optimal MDI therapy; or~~
~~3.2. In the opinion of the treating specialist a trial with an MDI therapy would be unsuitable and clinically inappropriate~~

3. In the opinion of the treating relevant practitioner the patient would benefit from an Automated Insulin Delivery (AID) system

~~*This includes permanent neonatal diabetes or patients with insulin deficiency secondary to cystic -fibrosis or pancreatectomy.~~

Renewal – (type 1 diabetes) from any relevant practitioner. Approvals valid for ~~3~~**6** months for applications meeting the following criteria:

~~Both:~~
1. Patient is continuing to derive benefit according to the treatment plan agreed at induction.
2. ~~There is objective evidence of maintained improvement in glycaemic control.~~

Discussion

7.2. The Committee considered that the proposed three-month initial approval duration was insufficient and should be extended to six months to allow sufficient time for individuals to access a funded pump. The Committee considered that this would align with any scheduled pump onboarding process timeframe. The Committee considered that this would help reduce delays in the health system.

7.3. The Committee noted consultation feedback which requested that carbohydrate counting education by a registered dietitian is included in the insulin pump eligibility criteria. The Committee considered that the specific inclusion of a requirement for carbohydrate counting was a clinical criterion rather than a funding criteria. The Committee considered that dietary education and carbohydrate awareness would normally be part of an individual's supporting work-up with a diabetes multi-disciplinary team.

7.4. The Committee considered that simplifying the Special Authority criteria for insulin pumps by removing requirements around hypoglycaemic events and Multiple Daily Injections (MDI) trials would reduce the prescriber burden. The Committee considered that simplifying the criteria would not lead to any significant impact on total population numbers and would align interpretation in the clinical community and improve equity of access.

8. Implementation

8.1. The Committee noted concerns that had been raised regarding the level of implementation support required to ensure a successful listing of CGM's and a transition for insulin pumps. The Committee considered that while onboarding a new individual requires a level of resource, support for people in the post-pump onboarding phase was more crucial and resource intensive. It was noted that resource availability was highly variable by region, and that the brands of insulin pump that were used by individuals varied significantly across regions.

8.2. The Committee noted that the prioritisation of specific diabetes population groups for insulin pump onboarding and transition to new insulin pumps was of concern. The Committee considered that prioritisation is currently being determined at the regional clinic level. The Committee noted that currently there is no nationally agreed prioritisation guideline however this is something that is likely to be addressed through the New Zealand Society for the Study of Diabetes or the Health New Zealand National Clinical Networks. The Committee considered that some regions may prioritise the transition of people currently receiving the Medtronic supplied pumps, and that this would likely occur in regions where the Medtronic market share is more significant.

8.3. The Committee considered that primary care would likely be the main pathway for individuals initiating CGM's and that it would be important to ensure that they have the appropriate resource and resources to support this, including educational material. The Committee considered that children would likely still be initiated onto CGM's via secondary care specialist diabetes teams. It was considered that pharmacies would be unlikely to have a significant role in onboarding individuals to CGM's. The Committee noted that it was important that the data produced from CGM usage was appropriately utilised to enable the maximum health benefit.

9. Criteria for Access to the Alternative Brand Allowance (ABA)

9.1. The Committee noted that the proposal for the supply of CGM's and insulin pumps and associated consumables had a provision for a 10% alternative brand allowance (ABA) which was intended to allow a funded option for those individuals for whom the proposed options would not be clinically appropriate. The Committee noted that this provision was not intended to be a target level but rather an upper limit for funded access to non-dual supply products.

9.2. The Committee noted that there had been a high level of interest expressed through the consultation feedback in relation to which individuals would be able to access other products as part of the ABA, and how this would be accessed. The Committee noted that the proposed extension of the insulin pump transition period from 12 months to 24 months would likely reduce the need for many individuals to consider accessing products through the ABA process.

9.3. The Committee considered that it would not be appropriate for prescribers to request access to an alternate CGM or insulin pump due to personal preference. The Committee recognised that the requirement for change may be difficult for some people however in almost all cases it would be possible to successfully transition to a funded solution with the appropriate support.

9.4. The Committee considered that it would be reasonable for an individual to access an alternative system via the ABA if they:

9.4.1. Suffered from a significant cognitive impairment or physical disability which would make it difficult to learn a new system. However, the Committee considered that this would unlikely be a sufficient basis for accessing the ABA if the individual had access to a support person who is able to facilitate a change to an alternate diabetes technology solution. The Committee considered that this would likely represent a small group of people.

9.4.2. Have difficult social circumstances. The Committee considered that a small group of people lived in very remote geographic areas which may have intermittent access to electricity, and may make a non-rechargeable, phone independent solution more appropriate. The Committee noted that the Ypsopump was powered by an AA battery and was not reliant on an external power supply, however it did require a phone to operate the AID algorithm. The Committee considered that there should be a facility whereby those people who don't own a phone should have the ability to access one.

9.5. The Committee considered that very high HbA1c levels (>80 mmol/mol) would not constitute a clinical rationale for access to the ABA. The Committee considered that the proposed products would be expected to provide the anticipated health benefits for this group of people.

9.6. The Committee considered whether there was sufficient basis to allow access to the ABA for young children who are currently using a solution not included in the proposal. The Committed considered that this would likely only be a basis if there were additional complex social circumstances involved, such as the individual living in a remote geographical location.

9.7. The Committee noted that newer AID algorithms for the Tandem t:slim X2 insulin pump, such as Control IQ 1.5, would be able to address the needs of individuals basis for accessing an alternate system through the ABA process.

9.8. The Committee considered that the issue of adhesive intolerance for CGM's is not a significant problem, particularly in adults where skin is generally more resilient. The Committee considered that in most people, including children, most skin issues can be well managed using appropriate skin preparation.

9.9. The Committee also noted that consideration should be given for individuals to switch to an alternate pump/algorithm where there is an absolute contraindication to the use of a particular control algorithm in certain clinical circumstances such as those undergoing complex renal replacement therapy e.g. ambulatory peritoneal dialysis.

9.10. The Committee was informed by Pharmac staff that discussions had taken place with various government agencies (including Health New Zealand – Carer Support / Ministry of Social Development – Disability Allowance) that are currently providing financial support for people with diabetes. The Committee noted that no changes had been proposed to these mechanisms/schemes and thus they would continue to be available to support individuals wanting to access a non-funded CGM and current recipient would continue to receive the benefit that they are currently accessing.