

Diabetes Subcommittee of PTAC meeting held 3 March 2011

(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 2008*.

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 5 & 6 May 2011, the record of which will be available in June 2011.

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1 Diabetes test meters and test strip review

- 1.1 The Subcommittee reviewed the information on diabetes test strip dispensing with other diabetes pharmaceuticals provided by PHARMAC extracted from pharmaceutical claims data. Members noted the average number of test strips collected by patients on metformin or diet alone appeared high when considered with international guidelines. Members noted that Best Practice Advocacy Centre (BPAC) had provided clinicians' guidance on the use of test strips and that the usage figures also appeared high compared to the BPAC recommendations. Members noted that the number of test strips used by patients on insulin appeared low compared to international guideline recommendations.
- 1.2 The Subcommittee considered that type I diabetics may over or under use due to their personal preference with respect to their diabetes and level of care. Members considered that patients currently had ample opportunity to access test strips and it was up to the clinician and patient to agree to the appropriate level of testing. Members did not consider that PHARMAC should enter into any campaigns to target testing in this patient group.
- 1.3 The Subcommittee noted that patients on metformin or diet alone were not eligible for subsidised blood glucose diagnostic test meters as these were only subsidised for patients on insulin or sulphonylureas or who were pregnant. Members noted that clinicians received sample meters from pharmaceutical companies to initiate patients on, which allowed this patient group access to a meter.
- 1.4 Members noted that clinicians often initiated newly diagnosed type II diabetics on test strips to allow them to see what effect diet and exercise have on their blood glucose. Members considered that long term testing may be more damaging as increased testing may lead to increased anxiety and worry. Members considered that patients should only be testing if they are likely to change something, for example the insulin dose they are about to use.
- 1.5 The Subcommittee noted that for type II diabetics, HbA1c was the appropriate test to evaluate glycaemic control. Members noted that the HbA1c 'speedometer' available to general practice and diabetes centres was an excellent tool to explain blood glucose control to patients. Members noted that prior to insulin initiation in type II patients it was appropriate to initiate regular blood glucose testing. Members noted that some clinicians were progressing directly to insulin from metformin in type II diabetics
- 1.6 The Subcommittee considered that there was likely to be an over use of blood glucose testing in rest homes.
- 1.7 The Subcommittee **recommended** that PHARMAC consider a campaign to promote optimal use of blood glucose testing strips aimed at the Primary Health Organisation (PHO) level. Members noted that this campaign should be targeted for practice nurses and general practitioners. Members noted that PHOs should have an education co-ordinator and that they would be the appropriate people to discuss this type of program with.

1.8 The Subcommittee reviewed the patient application for the funding of test strips for patients on home total parenteral nutrition (TPN). Members considered that patients with glucose intolerance may require test strips to monitor blood glucose; otherwise there was not any unmet clinical need. Members noted that patients receiving TPN in hospital were monitored and would not need to self monitor blood glucose.

1.9 The Subcommittee **recommended** that PHARMAC fund blood glucose test strips with a high priority for patients on home TPN with the following restriction:

Patients on home TPN at risk of hypoglycaemia or hyperglycaemia

1.10 The Subcommittee considered that patients with a disorder of glucose homeostasis, either acquired or genetic, could not currently receive funded blood glucose test strips. Members considered there were approximately 40 to 50 patients nationally who may require blood glucose test strips for a disorder of glucose homeostasis. Members noted that currently clinicians would be prescribing these and endorsing the script inappropriately or applying for Hospital Exceptional Circumstances.

1.11 The Subcommittee **recommended** the PHARMAC fund blood glucose test strips with a high priority for patients with impaired glucose homeostasis with the following restriction

Patients with a genetic or an acquired disorder of glucose homeostasis not including Type I or Type II diabetes or metabolic syndrome.

2 Continuous Subcutaneous Insulin Infusion (Insulin Pumps)

2.1 The Subcommittee reviewed a PHARMAC generated application for Insulin pumps. Members noted the significant number of responses to the PHARMAC request for information from clinicians, District Health Board, patients and suppliers.

2.2 The Subcommittee noted that insulin pumps were a method of delivering rapid acting insulin in both varying basal amounts and as a bolus when required. Members noted that insulin pumps were similar in action to multiple daily injections (MDI) of insulin, including long and short acting insulin, but allowed greater sophistication of dosage and control.

2.3 The Subcommittee considered the evidence for insulin pumps from randomised controlled trials (RCTs) was of moderate quality but weak strength for both improvement in control of HbA1c and also reduction of hypoglycaemic events. The Subcommittee considered the evidence for insulin pumps from observational studies was of moderate strength but weak quality for the same outcomes.

2.4 The Subcommittee noted that the RCTs excluded the population groups that it considered were most likely to benefit from insulin pumps, namely those with recurrent hypoglycaemic events. The Subcommittee considered that RCTs may target patients with already good glycaemic control, rather than those with less good control. The Subcommittee noted a confounder for insulin pump observational studies could be that the insulin pump acts as a 'talisman', in that the services surrounding the insulin pump may provide much of the benefit.

- 2.5 The Subcommittee considered that patients using an insulin pump used approximately 20% less insulin than those on MDI. Members noted that patients would maintain one or two vials or pens of long acting insulin at home in case of insulin pump failure. Members noted that patients would likely increase the number of blood glucose test strips prior to and post initiation of an insulin pump. Members considered that there would likely be a small increase in the usage of ketone test strips for patients on insulin pumps.
- 2.6 The Subcommittee considered that in its experience insulin pumps provided lifestyle benefits for patients and a definite improvement in clinical markers of diabetes including a reduction in HbA1c of between 0.5 and 0.7% and a reduction in the number of hypoglycaemic events. Members also considered it likely that insulin pumps provided greater glycaemic stability (lower peak and trough variation). Members considered that the Diabetes Control and Complications Trial was the seminal study for diabetes control with respect to outcomes.
- 2.7 The Subcommittee considered that patients on insulin pumps had an increased risk of ketoacidosis if the tube was occluded as there was less circulating insulin reserve, and that patients could rapidly develop ketoacidosis overnight if this occurred. Members also noted that patients had to be motivated to receive any clinical benefit and that if the patient (or caregiver) was not motivated then insulin pumps provided no benefit over MDI.
- 2.8 The Subcommittee considered that the benefit of insulin pumps in pregnancy is not well demonstrated. The Subcommittee considered there may be some merit where pumps facilitate control of HbA1c less than 6.5%, but it would expect much of this benefit to be lost if this level of control was not achieved in the first 8-10 weeks of gestation. Members noted that for patients wanting to become pregnant (and during early pregnancy) maintaining an HbA1c under 6.5 % may result in a reduction in foetal abnormalities. Members noted that currently pharmaceutical companies loaned insulin pumps to patients wishing to become pregnant and recovered them post partum, and that although this may be clinically defensible most patients wished to retain the pump.
- 2.9 The Subcommittee noted that there was currently a large inequity in New Zealand for the funding of insulin pumps and consumables from DHBs. In addition, funding from charities made it easier for some groups but not others to receive pumps. Members noted that Maori and Pacific Island Type I diabetics were less likely to access insulin pumps currently due to economic constraints. Members noted that if considered appropriate for funding that PHARMAC would likely fund both pumps and consumables. Members noted that the funding restrictions for consumables should be aligned with the requirements for the pumps to avoid patients that diabetic teams would not consider good candidates purchasing a pump, and gaining access to funded consumables [or vice versa].
- 2.10 The Subcommittee noted that funding of insulin pumps and consumables would require intensive nurse and clinician time. Members noted that there would be capacity limitations at that level which would be a rate limiting step in access in some DHBs.
- 2.11 The Subcommittee considered that patients should only be initiated on an insulin pump by a diabetic team. Members noted that patients should undergo intensive MDI prior to application for an insulin pump. Members noted that applicants should undergo training in carbohydrate counting, insulin pump usage and if possible undergo a psychiatric test.

- 2.12 The Subcommittee recommended that insulin pumps should be restricted as there was unlikely to be a benefit for all patients. Members considered that the New Zealand Society for the Study of Diabetes (NZSSD) 2008 recommendations were appropriate restrictions. Members noted that for paediatric patients the guidelines should include highly motivated patients with poor control, recurrent hypoglycaemia or early signs of disease progression (e.g. retinopathy) (or, interested, highly motivated caregivers if the patient is very young). Members also considered that co-morbidities should be eligible e.g. coeliac or cystic fibrosis patients.
- 2.13 The Subcommittee noted that patients should initially be reviewed after three months and then annually. Members noted that if patients were not showing a benefit then ongoing subsidy should be withdrawn. Members considered that NZSSD could be approached to advise on exit criteria.
- 2.14 The Subcommittee **recommended** that if PHARMAC was to provide subsidy for insulin pumps then PHARMAC should consider price, quality, warranty, service and back-up and an appropriate interface for ease of use.
- 2.15 The Subcommittee **recommended** listing insulin pumps and consumables for patients who meet the entry criteria with a high priority.