Insulin pumps consultation

Summary of issues raised and PHARMAC responses

June 2012

Executive Summary

This summary of submissions outlines the key themes from the submissions received on the consultation document 'Proposals relating to multiple diabetes products' dated 23 February 2012. A representative sample of submitters' responses are summarised under appropriate headings. This summary tries to reflect the content and tone of the submissions accurately. A PHARMAC staff response is also provided to detail how the proposal does (or does not) address the issue raised.

The consultation document was sent to all suppliers, patient groups, clinicians and other parties that, in the view of PHARMAC, may be affected by the recommendations contained in this paper. This included all parties who have previously expressed an interest in funding decisions relating to Diabetes products, including the New Zealand Society for the Study of Diabetes and Diabetes New Zealand. The consultation letter was also sent to all DHB hospitals and published on PHARMAC's website. The views included in submissions are set out in this summary, but these cannot be seen to reflect the views of all people who may be affected by the proposal.

Contents:

Supplier/industry responses		PHARMAC Response
	Reservoir size (200iu compared with which has 300 units); has slower infusion rates which may reduce the chance of 'tunnelling' and tissue damage at the site of infusion. The pump and consumables are more cost effective compared with Animas; Re Diabetes Subcommittee feedback – the proprietary batteries – the company provide extra batteries to reduce the chance of patients getting caught out; has a remote device	The current proposal allows for dual supply of insulin pumps, but only one pump is proposed for listing at this stage. If the proposal is accepted PHARMAC would likely release a Request for Proposals seeking a second supplier of insulin pumps. PHARMAC sought advice from NZMS regarding cartridge size. NZMS noted that based on independent data from the USA regarding insulin use, 92% of patients using insulin pumps use 60 units per day or less. Generally, type 2 patients use more insulin than patients with type 1 due to their insulin resistance and the proposed Special Authority criteria do not include type 2 patients. Site leakage is the result of a phenomenon called tunnelling. Tunnelling is not caused by the size of bolus doses however the effects of tunnelling are certainly more obvious with larger doses when it occurs. Tunnelling is caused by repeated trauma to the infusion site. This repeated trauma (usually tugging) accelerates the body's reaction to the foreign object inserted in situ hardening the tissue around the cannula. PHARMAC sought the advice of the Diabetes Subcommittee, regarding the proposals for the supply of insulin pumps and consumables. The Subcommittee advised that the pump proposed to be supplied by was just marginally acceptable in terms of functionality and durability.
	is the supplier of the pump and systems currently available in New Zealand. note that its bid was very competitive when compared with the NZMS bid. provide clarification around the pumps warranty if alternative consumables are used with it: *'We need to let PHARMAC, patients and healthcare professionals know that using untested consumables in pumps may result in the incorrect operation of the system (for example, 'no delivery alarms' may not be triggered as intended due to different back-pressure resulting from the*	The current proposal allows for dual supply of insulin pumps, but only one pump is proposed for listing at this stage. If the proposal is accepted PHARMAC intends to release a Request for Proposals for a second supplier of insulin pumps. PHARMAC consider that a competitive process would be justified in determining any second supplier and note that Medtronic would be invited to place a bid.

	different geometry of the reservoir) and may result in adverse clinical outcomes. Any damage to the pump may not be covered under the warranty if that damage is a result of using untested consumables'. note that it has a team of staff who are qualified and have many years' experience in supporting patients with insulin pumps.	warranty excludes damage caused to its pumps if the damage is caused by a non- consumable.
	noted a list of functional differences between its product and the NZMS product. Specifically: • Animas does not have an integrated meter/remote and pump, which means that patients must insert blood glucose readings into the device manually. This can lead to patient error. • When the batteries are changed in the Animas, the 'active insulin' drops to zero leaving individuals to remember how much insulin is still active in their bodies. • The Combo pump meter device has reminders to ensure patients retest after a hypo event or a hyper post meal and helps pumps to stay within the target range. The CareSens meter doesn't do this (lack of integration). • There is no recommendation of carbs on the Animas system when having a hypo, increasing the risk of under or over treating hypo's. • Risk of dosing errors due to having to press arrows up and down to get the exact insulin dose needed • The insulin cartridge is not visible through the pump, therefore pumpers will not be able to see how much insulin is left in the cartridge. also noted the economies to be obtained by its proposal due to reduced wastage or though the sparing use of its consumables: • the larger size of the pumps cartridge which holds 3.15 ml therefore needs to be changed less often • patients can use the cannula only packs rather than a complete set, or alternate between. considers that it would also be more economical to maintain those people using insulin pumps currently. Staying on the same pump would avoid patients having to retrain to use another product, saving clinician time and disruption.	PHARMAC sought information from NZMS the supplier of the Animas 2020 who noted the following points. • Batteries typically last for around 8 weeks. • NZMS commented that all pump users are trained to inject by pen in the presence of ketones. Pumps do not record boluses given by injection. For this reason all pump users should be taught how the pump calculates the insulin on board as part of standard safety protocols as part of their initial training. NZMS notes that this rule can easily be applied if needed when the battery is changed. • NZMS are unaware of any adverse events resulting from patients' insulin on board returning to baseline when patients change their battery • NZMS notes that each DHB it supplies pumps to has its own standard hypoglycaemia treatment protocol which should be followed by the patient. There are increasing trends to base hypoglycaemia treatment on weight. There is no risk of under or over treating hypos if patients follow their health care team's recommendations. • Dialling up the bolus keeps the control with the user and not the pump reducing the risk of delivering a miscalculated bolus. • Insulin should not be exposed to sunlight. The home screen on the Animas pump displays the number of units left in the cartridge and the user pre-sets the pump to warn them when the insulin remaining in the cartridge reaches a certain level. PHARMAC staff note that warranty excludes damage caused to its pumps if the damage is caused by a non-

	notes in its response that it does not warrant the pump if used with infusion sets other than It further reports that the conversion cartridges used with Medtronic pumps have caused harm in incidents in Norway and Sweden.	consumable. It has, however, also stated on its website Q&A that its pumps are compatible with the NZMS consumables.
	raise several issues with the proposal: • sole supply – one pump does not meet the complex needs of all patients with diabetes • sole supply – patients are vulnerable to supply failure and there is a risk that no other supplier will stay in the market • Continuity – will patients need to change the model of pump they use every 3 years? This would involve unnecessary re-training • The monopoly created by the incumbent supplier will enhance their market position and negotiating power in the next tender round • Warranty issues for using alternative consumables also note that medical technology has a short life cycle (typically 18 – 24 months) and a majority of new products bring added functionality and with insulin pumps, innovation brings improved management and subsequently better treatment of the diabetic patient.	PHARMAC's has not proposed a sole supply arrangement, rather the proposal is for dual supply with only one supplier proposed at this time. If the proposal is accepted PHARMAC staff intend to release a Request for Proposals for a second supplier of insulin pumps. PHARMAC considers that a competitive process would be justified in determining any second supplier. The contract is an evergreen agreement which means that patients would not necessarily be required to change insulin pumps after three years; this is merely the period of protection for the supplier. PHARMAC staff note that the agreement allows for the supplier to bring in a new pump with new technology (provided there are no objections from PTAC or the relevant subcommittee). PHARMAC would evaluate new technologies after the period of dual supply, and where there is proven health benefit from added functionality we would include this in our cost utility analysis. Non funded suppliers may choose to exit the NZ market; however PHARMAC's experience is that this is unlikely to occur and suppliers tend to compete for the market again following periods of sole supply. The current agreement allows for dual supply and PHARMAC intends to run a competitive process for a second supplier.

Legal questions	Comment from patients and patient groups	PHARMAC response
Breach of Patient Rights	'We believe that the current Pharmac Proposal breaches Item 4 – Proper standards – which states 'you have the right .. to receive services that reflect your needs'.	We believe that the proposed pumps and consumables would meet the needs of patients that meet the access criteria.
Breach of UN General Assembly Resolution on the Prevention and Control of Non-communicable Diseases – Sept 2011	NZ was one of the signatories who adopted the Political Declaration of this Assembly. Item 45c – according to national priorities. Increase and prioritize budgetary allocations for addressing non-communicable diseases... and treatment of non-communicable disease and the related care and support .. 45m... ensure the scaling up of effective, evidence based and cost-effective interventions that demonstrate the potential to treat individuals with non-communicable diseases, protect those at risk of developing them and reduce risk across populations'.	The proposal is consistent with PHARMAC's legislative objective, which is "to secure for people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided" The proposal would result in consistent national funding for insulin pumps and consumables, and PHARMAC staff consider that the number of people who would have access to funded pumps and consumables would be more than the current situation.

Technical/Clinical issues Comments from clinicians, Patient Groups and patients		PHARMAC Responses
Accu-chek has the lowest insulin infusion rates	This is sometimes essential for very young children and patients with neonatal diabetes. Having this as a 'second line' option would be useful. Accu-Chek Combo can modify basal rate in increments of 0.01 u. For example 0.26,0.27,0.28 whereas the Animas has only 0.025 unit increments. This ensures fine tuning of insulin requirements for very young or those with insulin sensitivity. Accu-Chek Combo has the capacity to increase the basal rate by 500% in times of serious illness, Animas only allows 200%.	The supplier of the Animas 2020 notes that this insulin pump continually offers the user an increment of 0.025u/hr regardless of the dose. The supplier further notes that although the Accu-Chek Combo can deliver in increments of 0.01u/hr at lower basal rates, the lowest basal rate that can be delivered is 0.05u/hr. NZMS advises that its experience has shown that the only patients that really would benefit from a 0.01u/hr basal rate increment are premature infants where the requirement of the lowest basal rate of 0.025u/hr is more important than the increment. The Animas 2020 pump enables a user to increase +200% (which is 3 x the programmed rate). NZMS notes that in rare cases where an increase of 500% is required the increased basal rate could be achieved by setting up a new basal programme.
Issues with warranty and safety of operation.	Using other consumables (infusion sets, cartridges) may invalidate the warranty on the pumps. Warranty of Medtronic and Accu-chek pump if using Animas consumables	PHARMAC considers that patients with a current insulin pump who meet the eligibility criteria for a funded pump and consumables should be advised that their existing pump warranty may not cover the use of NZMS consumables. If a patient did not want to use non-funded consumables with their existing pump they could continue to self-fund consumables. Alternatively the patient could apply for a funded pump if they used funded consumables with a different brand pump and that pump failed.
Animas do not have a continuous glucose monitoring system (CGMS)	The Medtronic pump and its Carelink downloading system allow us to remotely micromanage a child's pump and this system should be considered for funding'.	A number of patients are using pumps that have a CGMS component to them, an added feature that can be very useful for patients and health professionals. At this time PHARMAC has not considered funding of CGMS, and we would welcome an application for funding for this technology. The current agreement allows for dual supply and PHARMAC intends to run a competitive process for a second supplier.

Tubing length	30cm is useful for paediatrics. Long lines can get caught leading to site damage.	PHARMAC intend to release a Request for Proposals for a second supplier of insulin pumps and consumables and note the request for the 30 cm tube length, however in its self we do not consider this issue a reason not to accept the proposed pump.
Animas reservoir size	This is only 200 units – therefore patients using more than 50 units would need to change the reservoir more often than 3 days – increases cost.	PHARMAC sought advice from NZMS regarding cartridge size. NZMS noted that based on independent data from the USA regarding insulin use, 92% of patients using insulin pumps use 60 units per day or less. Generally, type 2 patients use more insulin than patients with type 1 due to their insulin resistance and the proposed Special Authority criteria do not include type 2 patients.
Cartridge seal not within the proposal	This should be funded.	The battery cap is included in the proposal because it is a requirement that they are regularly changed. The cartridge caps do not regularly need to be replaced. NZMS has advised that replacements would be carried in stock for patients who either lose or damage theirs.
Remote functionality	The Roche Combo has a Bluetooth/remote device which has the ability for a parent to deliver a bolus dose of insulin remotely to a playing child.	The proposal for blood glucose meters and test strips would provide on-going access to test strips for current users of the Roche Combo pump.
	Data on the pump can be transmitted to medical professionals via the web. Animas may not have this function?	The Animas pump is easily downloaded to a web based software application called Diasend which incorporates graphs and charts.
	The Bluetooth remote device allows a blood glucose reading to be taken, and the device can calculate the dose of insulin to give. For the Animas pump, the blood glucose reading needs to be entered manually, which may be an issue for children, people with dyslexia or who have sight impairment.	The proposal for blood glucose meters and test strips would provide on-going access to test strips for current users of the Roche Combo pump. In PHARMAC's view, a case that the remote function provides additional health gain has not yet been made. The remote comes at an additional cost (including test strips). We note this loss of functionality is one of the trade-offs having to be made in balancing price with functionality of the pumps. .
	Many patients wear their pump discretely under their clothing. It is necessary to access it in order to administer a bolus dose, however if the pump has a remote function, this is not necessary. 'Loss of remote functionality also increases the frustration and time taken to obtain results and deliver insulin; this can lead to an increase in missed boluses.'	

Animas has a higher bolus speed	This may lead to discomfort in some patients, especially those on high dose bolus. This might result in cannula leakage and sit discomfort and more frequent site changes.	PHARMAC sought the advice of NZMS regarding its pump, specifically site leakage. NZMS noted the following: Site leakage is the result of a phenomenon called tunnelling. Tunnelling is not caused by the size of bolus doses however the effects of tunnelling are certainly more obvious with larger doses when it occurs. Tunnelling is caused by repeated trauma to the infusion site. This repeated trauma (usually tugging) accelerates the body's reaction to the foreign object inserted in situ hardening the tissue around the cannula. NZMS noted that pain is also usually related to the site being inserted incorrectly e.g. too shallow or the incorrect cannula length being used. NZMS considers that this issue can also be resolved with additional support or the use of alternative sites. NZMS note that they have not experienced any issue with more frequent site changes due to the bolus speed when the pumper is replacing their infusion set as recommended.
Screen is difficult to read	The numbers are quite small to read Outdoors, the screen is difficult to read without complete shading.	PHARMAC note that the animas 2020 pump has a full colour screen which appears easy to read.
Alarms/Alerts/Graphs and Tools	The Animas pumps only beep or vibrate but not at the same time. The Accu-chek Combo pump has Data Management graphs and charts on the pump. The Animas pump does not have a predictive occlusion alarm like Accu-chek Combo does The Animas pump does not have any immediate options for specific events in time like activity, sport, or illness. The Animas pump doesn't have customisable menus	PHARMAC staff questioned NZMS regarding the specific functionality of the Animas 2020 pump. NZMS provided the following response: The pump can be set to beep or vibrate based on user preference. Pump users sometimes prefer discreteness and do not want the pump to provide audible warnings when they are out. If the pump is set to vibrate alarm and no action is taken within one hour sound will also automatically be activated so both occur. If the pump is set to audible alarm and no action is taken within one hour the vibrate function will automatically be activated so both occur. NZMS is not aware of data management graphs being displayed on the Combo pump, but note this could be included in the remote device. Animas does not have graphs and charts

		on the pump but it is easily downloaded to a web based software application called Diasend which incorporates graphs and charts. The 2020 absolutely detects occlusions like every brand of pump does. NZMS do not think any pump would be allowed on the market without this. Up to four different basal profiles can be pre-set and named according to user preference for specific events. Temporary rates can also be run as required. The Animas advanced set up menu customises user preference for everyday use of the pump. This includes ISF according to time of day, BG targets according to time of day, Insulin to Carbohydrate ratio according to time of day, Personalised basal programmes (up to 4). Advanced features can be turned off by user so they do not appear on the menu. The Animas pump also features customisable ring tones, and a food database unique to the user.

Old technology	We understand that Animas 2020 pumps are being phased out overseas. Will NZ become a dumping ground for older technologies that come at a good price and will product support be assured if this is an end of line product? Several respondents commented that they believed the Animas 2020 was old technology and that it is not being sold in the US anymore. Are pumpers just getting the end of line stock so it can be used up?	All PHARMAC agreements with suppliers of diabetes devices allow for the supplier to upgrade their technology without penalty. The dual supply period proposed is for up to three years and at the end of this period new suppliers would be able to enter the market. The agreement with NZMS allows for the supplier to bring in a new pump (provided there are no objections from PTAC or the relevant subcommittee). PHARMAC would evaluate new technologies after the period of dual supply, and where there is proven health benefit from added functionality we would include this in our cost utility analysis. PHARMAC requested information from NZMS regarding the Animas 2020 and whether it was being phased out overseas. NZMS response is as follows: • NZMS notes that its pumps are manufactured to order. The technology of the 2020 is tried and trusted and still has more functionality and newer technology than some of the newer competitor pumps. In addition the 2020 has the technology to include smart features directly on the pump without requiring a separate device to access them. • NZMS commented on the One Touch Ping (the newer pump). NZMS considered its benefit was that the blood glucose is transmitted from the One Touch glucose meter to the pump via radio frequency. The Ping pump uses the same platform as the 2020 pump and there is very little difference in the functionality or operating menu of the pump other than the glucose meter pairing. The test strips that the One Touch Ping meter uses are not reimbursed in NZ and so there was no point in bringing it here. NZMS further noted that there are also issues with radio frequency laws internationally and NZMS believe that the Ping was only ever released in the USA and Canada because of this.

Alternative Funding mechanisms Comments from clinicians, Patient Groups and patients		PHARMAC Response
Provide a set dollar amount for patients to purchase the pump of their choice		PHARMAC's policy is to fully fund new pharmaceuticals or not at all. Part funding maintains a cost barrier for patients, and leads to inequity of access. This is contrary to PHARMAC's legislative objective. . Fully funding a pump for all eligible patients provides greater surety of the health benefit. . Proposals for sole and dual supply, in PHARMAC's opinion, result in lower prices in the longer-term allowing, releasing funds for greater investment in health and, ultimately, better health outcomes overall..
PHARMAC consider Medtronic pumps as the dual supply pump and soon so that Medica, the company marketing them in NZ are not forced from the NZ market due to stopping for Optium strips. The loss of the company would impact on the resources and support that we can offer clinically, particularly in regard to the CGMS which is the only CGMS system currently in use in NZ approved from paediatric use.		The current proposal allows for dual supply of insulin pumps, but only proposes listing one pump at this stage. If the proposal is accepted PHARMAC intends to release a Request for Proposals for a second supplier of insulin pumps. PHARMAC considers that a competitive process would be justified in determining any second supplier. Medtronic would be invited to bid.
Patients using self-funded or funded pumps other than Animas should be eligible for grand-parenting on their current pump.		The blood glucose test strips and meters proposal includes exemptions to allow patients currently using the Roche Combo pump to continue to do so. This recognises that patients would be disadvantaged if the exemption did not occur. The current proposal allows for dual supply of insulin pumps, but only proposes listing one pump at this stage. If the proposal is accepted PHARMAC intends to release a Request for Proposals for a second supplier of Insulin pumps. Patients who meet the funding criteria may be eligible for a new pump under this proposal
Need more than one pump or brand of consumables funded	One type of pump won't suit everyone (i.e. the cartridge size and the amount of insulin) and patients use different infusion sets to suit their needs/preference'. Some patients develop allergies to the adhesives on infusion sets therefore they should have access to consumables which do not cause skin reactions.	The current proposal allows for dual supply of insulin pumps, but only proposes listing one pump at this stage. If the proposal is accepted PHARMAC intends to release a Request for Proposals for a second supplier of Insulin pumps. We note that reduction in choice of meter is one of the trade-offs having to be made in balancing price with functionality of the pumps.

Patients using Accu-chek combo pumps will be disadvantaged	Accu-chek Combo pumps can use Animas consumables but still require their own branded consumables (which are not funded under this proposal) – cost $26.45 The remote device will be unusable if Accu-chek Performa test strips are not funded. There are particularly useful in children as the remote function means a parent/teacher can be in control of using it while the child engages in normal activities.	The blood glucose test strips and meters proposal includes exemptions to allow patients currently using the Roche Combo pump to continue to do so. This recognises that patients would be disadvantaged if the exemption did not occur. If the proposal is accepted, patients eligible for a funded pump and consumables should be advised that their existing pump warranty may not cover the use of NZMS consumables and that they should talk with their clinician about whether they should use NZMS consumables with their existing pump. If a patient chose to use funded consumables with a different brand pump and that pump failed, they could immediately access a funded pump. If a patient did not want to use non-funded consumables with their existing pump they could (a) continue to self-fund consumables; or (b) immediately switch to the funded pump
Suppliers supporting existing pumps	There is a risk, should any insulin pump suppliers leave NZ, that repairs and maintenance and support of existing pumps will not be available.	PHARMAC understand that existing insulin pumps have a warranty that must be honoured by suppliers. There is likely to remain a private market for those patients who do not meet the criteria for funded insulin pumps and PHARMAC envisages that pump suppliers would continue to supply pumps to these patients.
Continuity of patients receiving funding through DHB initiatives may now have to pay	Although we applaud PHARMAC for entering into a provisional agreement with NZMS to fund Animas 2020 insulin pump, we are saddened that access to our current pumping benefits will be reduced to allow the rest of the country to catch up. The (Diabetes Patient Group) would now have to meet extra costs to enable funded access. ‘We cannot see why instant sole supply is necessary in this situation, when a subsidy of $4,500 would go a long way to purchasing nearly all the pumps currently on the market. There is a high potential cost to PHARMAC here in that eligible patients using other pumps would transfer to Animas at an immediate cost of $4,500. This would involve a deplorable physical and financial wastage of current functioning pumps.	PHARMAC's model of sole supply or dual supply historically has provided lower prices which allow more patients to be treated with the limited funding available. Initially a high price may be paid to create a market which allows for further savings into the future. The current proposal allows for dual supply of insulin pumps, but only proposes listing one pump at this stage. If the proposal is accepted PHARMAC intends to release a Request for Proposals for a second supplier of Insulin pumps.

Distribution of pump and consumables	We think that the insulin pump should be supplied to the multidisciplinary team to prevent any person or family from starting the pump without medical guidance. Consumables should be available through community pharmacy. We think there is a strong potential for distribution to become a messy process with other health professions involved with limited knowledge on pumping. Ideally elimination of unnecessary 'loops in the chain' would be ideal.	PHARMAC considers that a distribution system via community pharmacy would be appropriate for insulin pumps and consumables. With national funding of insulin pumps and consumables it is appropriate that a patient has access to insulin pump consumables from any community pharmacy to ensure improved access. For funding purposes a prescription would still be required and this would require a prescription from a Doctor or nurse specialist.
Loan pumps/trial period	Most companies currently offer a free 6 week trial of the pump and this is routine in our practice, so that patients can confirm that they have no issues being continuously connected to a medical device.	The Diabetes Subcommittee (20 April 2012) considered that a pump trial would not be necessary for most patients as long as the clinician applying for funding was satisfied that the patient was suitable and had done an appropriate psychological assessment.
More than one box of consumables may be needed	An extra box (13 per year) should be provided. In addition for some patients needing to use more cartridges due to the small size, they may also need to change the site. Also, sometimes insertion of a site doesn't work and infusion sets can be wasted.	PHARMAC has proposed a restriction of 3 sets of infusion sets and cartridges per prescription and a limit of one prescription every 90 days. The cost effectiveness of insulin pumps and consumables is dependent on price and if patients change the sets more often this dramatically affects the cost, and therefore the cost effectiveness of the decision. The intent of the restriction is that patients should receive 30 days usage from each infusion set and cartridge. PHARMAC staff note that the proposed maximum number of sets a patient can access in a 12 month period is 13 packs which should provide some overage in case of site failure.

Resource/Financial Patient groups, clinicians		PHARMAC response
Comments about NZMS	We have had a positive experience with NZMS's urgent replacement policy and 24 hour technical support for our patients and medical teams, as we have from all companies with whom we've been involved	Comment noted.
Resource involved with re-initiating on pump should a switch be needed	There may be better efficiency if consumables were funded for all pumps and switch occurred at end of pump life	PHARMAC has entered into a dual supply arrangement that does not allow for more than one other insulin pump and associated consumables to be funded. PHARMAC's experience is that over time competition leads to lower prices and allows more patients to be funded for the same cost.
Funding for increased number of patients initiating on pumps	This will require increased resource. Who will provide this? Who will fund the CHO counting education? Pump education is lengthy and requires a lot of support. Currently, the situation is that if a patient is deemed to be suitable, the supplier does the teaching with the diabetes team and helps with adjustments of insulin to improve control.	Services and service levels are determined by the individual DHBs. PHARMAC understands many DHBs already have Specialist Diabetes Services and that these would be best place to understand the service requirement and how to best use their limited resource. Advice to PHARMAC from clinicians was that suppliers of insulin pumps should only provide technical support. Clinical advice regarding insulin should only be provided by clinicians. NZMS is contractually obliged to provide education, training and support services to patients, clinicians and nurses, to the same level they are currently supplying these services at the date of the agreement
Expertise within each DHB will be varied	What assurances are there that potential insulin pump users have access to a multi-disciplinary team? In more rural areas, will these teams be available to these populations?	It is PHARMAC's understanding that many DHBs already utilise a collaborative system for patients on insulin pumps. It is up to individual DHBs to align services.
Establish protocols	One organisation noted and agreed with written protocols for training on starting on pump therapy. Training does need to be thorough and it takes time. Unless the potential recipient is willing to commit to really understanding and using the technology, the return may be less than satisfactory and could potentially be dangerous',	Comment noted.

Training	Pharmacists will require extensive training in order to appropriately advise patients on the use of their pump and of the pumps associated consumables.	PHARMAC envisages that initiating prescribers would train the patient in the use of the pump. We would encourage pharmacists to up skill to understand their patients' needs with respect to pumps.
Does the requirement for a multidisciplinary team disadvantage rural populations	To ensure nationwide eligibility there would need to be defined access criteria and funding for units in smaller DHBs to nearest pump teams for initiation and overall supervision, though routine care could still occur in in the DHB of residence.	DHBs service configuration is outside of the PHARMAC process, however we understand that smaller DHBs already work with larger centres with respect to diabetes care.

Proposed Eligibility Criteria Comments from clinicians and Patient Groups	PHARMAC Response
Neonatal diabetes (the evidence suggests these patients should start CSII from diagnosis) including pancreatic agenesis	PHARMAC sought clinical advice from the Diabetes Subcommittee and has amended the Special Authority to include neonatal diabetes. Pancreatic agenesis is a rare cause of neonatal diabetes mellitus
Pancreatectomy	The proposal has now been amended to include this patient group as advice from the Diabetes Subcommittee of PTAC was that pancreatectomy presents with similar health outcomes as type 1 diabetes.
Patients with cystic fibrosis: The Cystic Fibrosis Association of New Zealand requested the appropriate justification for the specific exclusion of patients with CF- related diabetes. It is interested to hear which clinical and benefit differences PTAC has observed between Type 1 diabetes and CFRD, that would have led to this exclusion from accessing insulin pumps, which have been proven, in clinical practice, to have high efficacy in controlling glycaemic fluctuations in this vulnerable patient group, who have chronic issues with glycaemic control due to the demands of their diet with regard to their cystic fibrosis.	We have not assessed the evidence for insulin pump therapy in this population of patients at this time. We have received support from clinicians that insulin pumps be funded for patients who have developed poor beta cell function. The Diabetes Subcommittee of PTAC noted at its 20 April 2012 meeting: *Members also considered that some patients with cystic fibrosis who are severely insulin deficient would benefit from insulin pump therapy. The Subcommittee considered that further analyses be done to establish the cost-effectiveness of insulin pump in these patients.* At this time PHARMAC staff note that most of the benefit of insulin pumps is the reduction in long term complications, by reducing the HbA1c. This is based on combining evidence of HbA1c reduction in Type 1 diabetics on insulin pumps and the long term effects of HbA1c in type 1 diabetics. PHARMAC staff will provide a completed cost utility analysis for this patient group within four months. This is intended to coincide with a potential decision paper on the proposed RFP for a second supplier of insulin pumps.

Pregnant women or women who are planning pregnancy (up to 6 months prior to conception)	We have assessed the benefits of insulin pump use in this population of patients, and consider that insulin pump therapy is poorly cost effective. In addition the clinical evidence did not provide support funding for this group at this stage as noted below: Diabetes Subcommittee 3/3/2011 *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.* PHARMAC would be willing to consider an application for funding with new evidence for this patient group.
The following patient groups were raised as groups that may benefit from an insulin pump: • Coeliac disease. • Patients with insulin allergy • Gastroparesis • Eating disorders • Severe needle phobia	PHARMAC considered a range of patient groups for funded insulin pump access, and sought advice from its diabetes sub-committee. The proposed access criteria are considered to be those patients most likely to benefit clinically from access to a funded insulin pump, which assists with the cost-effectiveness of the proposal. Patients with type 1 diabetes who also have any of these conditions are eligible for insulin pump funding provided they meet the entry criteria (HbA1C or hypoglycaemia).
Children under 12, particularly under 5 years old (pumps offer small doses of insulin, less injections, improved QOL,	The Special Authority does not prohibit patients on the basis of age; it is designed to target those patients who are likely to show the greatest health benefit from insulin pump usage. Children under 12 are included in the proposed criteria and paediatric patients in whom trials of MDI are inappropriate (the youngest patients) are specifically mentioned.
Are there exemptions for patients?	There are no specific exemptions for patients however the exceptions process for consideration of patients remains available for patients under the Named Patient Pharmaceutical Assessment process.

Carbohydrate Counting	Could this be amended to 'patient and/or parent have undertaken a CHO counting course? Young children are not able to learn CHO counting'.	For the avoidance of doubt PHARMAC considers the intent of the Special Authority extends to caregivers of people with diabetes. PHARMAC has amended the criteria to state carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional). Health professionals should ensure the education being provided to patients should be targeted to each patient's requirements and consider that health professionals would act under their requirements of the Health Practitioners Competency Assurance Act. Carbohydrate counting is a method of matching your insulin requirements with the amount of carbohydrate you eat and drink. DHBs are responsible for the provision of services in their regions, including the funding of carbohydrate counting education if required. Individual DHBs would determine if funding would be made available.
	The criteria should be rephrased as carbohydrate counting education as many patients receive 1:1 education rather than attend a formal course such as DAFNE. We suggest that in addition, the patient must be 'actively and accurately practicing this skill as evaluated by a dietitian'.	
	A paediatric dietician may be more appropriate – a course geared for adults would not be appropriate for children.	
	Dietitians NZ recommended that criterion 3 be amended to read: 'Patient has undertaken carbohydrate counting education with a registered dietitian and is competent to undertake this'.	
	Define CHO course.	
	Who will fund the CHO counting education?	
Why should funding be restricted to people with poor control?		The intent of the Special Authority is to target those patients who attempt tighter control but cannot achieve this from currently funded therapy. Those patients who are not controlling their diabetes due to lack of engagement are unlikely to meet the funding criteria. Those patients who are well controlled on conventional therapy are unlikely to show any additional clinical benefit from an insulin pump. PHARMAC is not proposing to fund insulin pumps for lifestyle benefits.
How would the eligibility of existing pump users be assessed?		Patients would be assessed against the criteria prior to their initiation on a pump and the benefits shown since initiation. The Insulin Pump Panel would evaluate patients based on their clinician's applications and the provision of the patient's history.

The definition of benefit that would allow for renewal of subsidy of funded consumables states a 1% reduction in HbA1c from baseline. For some, that baseline was established over a decade ago and in the case of teenagers and young adults, would have been pre puberty or pregnancy when lower HbA1cs may well have been easier to achieve		Patients would be assessed against the criteria prior to their initiation on a pump and the benefits shown since initiation. The Insulin Pump Panel would evaluate patients based on their clinician's applications and the provision of the patient's history.
Criteria 2 1. Is a paediatric patient and in whom a MDI regimen trial is inappropriate; or 2. Is an adult patient and has adhered to an intensive MDI regimen using analogue insulin's for at least six months; but still has either a. four severe unexplained recurrent hypoglycaemic episodes over a six month period either due to hypoglycaemic unawareness or to nocturnal hypoglycaemia; or b. unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c and in the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol (1.0%) using insulin pump treatment; and c. has been evaluated by the multidisciplinary team for their suitability	Add 'early signs of disease progression such as mild or moderate retinopathy especially in children and young people with type 1 diabetes'; add 'frequent self-monitoring (minimum of 4 capillary blood glucose tests daily) as a pre-requisite 'Extreme insulin sensitivity' is not included in the criteria but is common in young children. These children should not have to have severe hypoglycaemic incidents to fit the criteria. Intensive MDI regimen (may be defined differently for paediatric patients).	Advice to PHARMAC from the Diabetes Subcommittee was that funded insulin pumps should be targeted to those patients who cannot adequately control their HbA1C using funded insulin therapy. Patients who are showing deterioration due to diabetes and are unable to reach control with conventional therapy would be eligible. The clinical recommendation was that patients must be engaged with treatment to achieve a benefit from an insulin pump. PHARMAC staff consider that patients with extreme insulin sensitivity would likely be able to meet the requirements for entry under the HbA1c entry criteria: unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c and in the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol using insulin pump treatment.
	We would recommend that the trial of the intensive MDI regimen should include the possibility of trialling both Glargine and Detemir insulin (currently unfunded).	The proposed Special Authority does not preclude the use of both glargine and detemir; however at this time PHARMAC has not been able to reach an agreement with the supplier of detemir insulin and therefore cannot require patients to undergo a trial of this insulin. Insulin glargine is the only funded long acting insulin and therefore PHARMAC consider that patients should only have had to trialled this long acting insulin.
	One clinician noted that the 3 month MDI trial is too short, and that all referred patients should have undergone at least 6 months of intensive supervision from an expert MDT. Many patients have been on MDI but have never been adequately educated or closely	PHARMAC staff have amended the proposed Special Authority criteria to state that a 6 month trial of MDI is required. The two periods (intensive MDI using analogues and hypoglycaemic events) would be concurrent.

for insulin pump therapy, or	supervised. This point is unclear and seems to suggest that people need to be in an uncontrolled state for up to 6 months which does not fit with the statement 'using analogue insulin for at least 3 months'. Are the two periods consecutive or concurrent?	
	We suggest that an upper level of acceptable HbA1c be set at 85 mmol/mol to ensure that only patients compliant with insulin therapy on MDI are accepted for funding.	The proposed entry criteria for funding of an insulin pump would require that a patient has adhered to an intensive MDI regimen using analogue insulin for at least six months. PHARMAC staff consider that the proposed restrictions would ensure that only appropriate patients would be accepted for funding.
Criteria 2.1.1 four severe unexplained recurrent hypoglycaemic episodes over a six month period either due to hypoglycaemic unawareness or to nocturnal	'We feel that four severe unexplained recurrent hypo's is excessive and potentially dangerous. We would suggest 'disabling hypoglycaemia' as recommended by NICE.	PHARMAC acknowledge that a hypoglycaemic event can be difficult for the patient, however the health related benefit of avoiding a severe hypoglycaemic event is estimated to be relatively small compared to the benefit of other treatments. The requirement for four hypoglycaemic events was chosen as it was the highest that was felt clinically appropriate while achieving health gains and reducing health sector costs to a level that put insulin pumps ahead of other funding options not taken by PHARMAC. PHARMAC prefers to include objective measures in special authority criteria, this helps provide consistency in prescribing and access by patients. An example of this is in the renewal criteria for patients with raised HbA1c, there is a requirement to lower HbA1c by 10 mmol/ml.
	We consider that the requirement to have 4 severe hypoglycaemic episodes over 6 months is totally excessive and unreasonable, both in number and in the short period concerned. Two severe episodes over a 12 month period would be far more appropriate, severe being defined as the usual 'third party' assistance requirement.	
	Alternative criterion: Significant hypo unawareness which persists despite appropriate interventions by the diabetes team' and 'pronounced dawn phenomenon which cannot be adequately managed MDI (ideally proven using continuous glucose	

	monitoring).	
	Many would additionally feel that frequent moderate hypoglycaemia, sufficient to disrupt work, school or family life is also a realistic indication as is refractory hypoglycaemia unawareness at least for a pump trial.	
	Stipulating 4 episodes of major hypoglycaemia is impractical and has a quantitative aspect missing in the other criteria. I suggest 'continued severe hypoglycaemia over a 6 month trial period on intensive MDI particularly at night or with clinical evidence of hypoglycaemic unawareness'.	
Criteria 2.1.2 unpredictable and significant variability in blood glucose including significant hypoglycaemia affecting the ability to reduce HbA1c and in the opinion of the treating clinician, HbA1c could be reduced by at least 10 mmol/mol (1.0%) using insulin pump treatment	This is a difficult criteria to define, but we are in general in agreement that objective evidence of a sustained reduction in HbA1c should be required if hypoglycaemia reduction is not the primary aim. We would however suggest that now we are using mmol.mol that this should be by 10 mmol/mol. A six month trial would also provide 6 months of capillary glucose data in graphical form which would a useful source of information for assessment.	The proposed Special Authority has been amended to include 10 mmol/ml.
Criteria 4.0 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care	Add 'that starting on a pump be done in conjunction with a paediatric endocrinologist with a multidisciplinary team' – important for children	PHARMAC considers that clinicians would act within their Vocational Scope and that if initiating a paediatric patient was outside of this scope that advice would be sought.

Renewal 1.3 ‘or maintains an HbA1c of <59 mmol/mol or 7.5% (as stated in the ISPAD and APEG guidelines)		The renewal requirements set criteria for an improvement for HbA1c of approximately 1% (10 mmol/ml) which the evidence suggests provides a long term benefit in reducing progression of complications of diabetes. A dose reduction from 7.6% to 7.4% is not likely to provide significant health outcome improvement.
Renewal 1.4 or a decrease in HbA1c by 0.5% during pump treatments (rather than from baseline and rather than 1% in those already established on a pump)		The renewal requirements set criteria for an improvement for HbA1c of approximately 1% (10 mmol/ml) which PHARMAC considers provides a long term benefit in reducing progression of complications of diabetes, so yes the requirement is a sustained 1% reduction.
Please confirm/clarify that it is the expectation that a person with diabetes would be able to keep a sustained HbA1c at 1% from the original baseline		
The criteria should include other measures of benefit, or a total view of benefit including mental health, should be introduced into in addition to the clinical measures. Some patients without extreme episodes of hospitalisation may not meet the criteria.		The proposed criteria have been developed based on clinical advice to target the areas of greatest health benefit.
Criteria additions/wording amendments for entry	We suggest that an upper level of acceptable HbA1c be set at 85 mmol/mol to ensure that only patients compliant with insulin therapy on MDI are accepted for funding	Patients who are unable to achieve a target HbA1C without suffering from hypoglycaemia who have adhered to intensive multiple daily insulin injections would be eligible for treatment. This does not preclude patients who may have a higher HbA1C prior to initiating on a pump.
	Co-ordination of a trial of the insulin pump with the induction training - we believe that it needs greater clarity that trialling can only be commenced after the training and under supervision of a suitably qualified person	PHARMAC note that this is a practical consideration that cannot be managed by Special Authority criterion but rather by clinicians. We anticipate that clinicians would work within their vocational scope and the requirement to be part of a multidisciplinary team should ensure that only adequately trained staff are initiating patients on insulin pumps.
Definitions needed in criteria	Relevant specialist – ‘From a Diabetes Specialist Service view point, relevant specialist would be someone with advance specialist diabetes knowledge and a working knowledge of insulin pump therapy (diabetes/endocrine physician, specialist diabetes paediatrician or a Nurse Practitioner diabetes).	The proposed Special Authority has been amended to state the applicant is a Vocationally Registered Medical Practitioner or Nurse Practitioner. Clinicians are expected to work within their scope of practice as determined by their College and therefore only clinicians who have a working knowledge of insulin pump therapy should be making applications. The proposed Insulin Pump panel would also be requiring applicants to describe the service they are providing for insulin pump patients.

	It would be wise to specify the expectation of a team psychologist	PHARMAC staff anticipate that Vocationally Registered Medical Practitioners working within their scope of practice would be aware of the definitions of these terms. As the applicant would be applying to an insulin pump panel, where there is confusion regarding the interpretation of a term this could be clarified during the application process.
	Define ‘Suitability’ for insulin pump therapy	
	Define ‘significant variability in blood glucose’	
	Multi-disciplinary team – medical, nursing, dietetic +/- psychology	
	What qualifies as a severe hypoglycaemic episode?	
	Please define ‘compliant’	