

# **Insulin pump therapy for type 1 diabetes**

## **Proposed criteria for approval**

**Dr Tony O'Sullivan, Hon Secretary  
On behalf of the Professional Services Committee,  
Diabetes Federation of Ireland**

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## Introduction

Insulin pump therapy (or continuous subcutaneous insulin infusion, CSII) represents an important innovation for patients with diabetes requiring insulin. It is safe and effective, and offers motivated patients a means to achieve glucose control equivalent to that of intensively-treated patients in the Diabetes Control and Complications Trial (DCCT) of 1993. Indeed, many patients involved in that trial were pump users, which indicates how long-established this method has become in the US.

This document outlines briefly the costs and benefits of CSII, and predicts likely new initiations over the next 2 years. The balance, and low activity levels anticipated, should make automatic approval of each application possible for the foreseeable future.

## How is pump therapy different?

Pumps deliver insulin at continuous **basal** rates that are fully programmable, in a way that cannot be matched by intermittent injection of longer-acting insulins, the only alternative available to non-pump users. Essentially intermediate-acting insulins have a peak of activity at some point during their duration of action, and very long acting insulins require large doses to deliver a reasonable basal insulin, with consequent concerns about weight gain and prolonged hypoglycaemia.

Longer-acting insulin injections further suffer from wide variability in insulin action when the same dose of the same insulin is given to the same person on successive days. Pumps only deliver rapid acting insulins and do not seem to suffer from this variability, giving more predictable control.

Pumps also deliver **bolus** insulin doses at mealtimes. These doses can be fully tailored to the meal and pre-meal glucose level, in that dose increments of 0.1 unit are possible (compared to 1 or 2 unit increments with pens and syringes). This enables tighter control as with pen or syringe injections the person with diabetes is often faced with a choice of, for example, taking 11 or 12 units with a meal, knowing that 11 will not be quite enough, and 12 will almost certainly cause a hypoglycaemic episode.

In addition, only a pump can deliver a mealtime bolus over a period of time when appropriate. These 'Square wave' and 'dual wave' boluses are relevant when a meal is taken over a longer duration, such as at a buffet or barbecue. Added value arises from the ease of use for those with visual impairment, as pumps can be primed to give audible confirmation prior to injection. Perhaps the most important aspect is the reduction in insulin requirement, typically by 30%, on changing to pump therapy.

Further pump benefits include reduction in nocturnal hypoglycaemia, and greater mealtime flexibility for patients with variable working or living conditions.

Overall, all of these factors contribute to more effective control of the patient's glucose levels. As even a 0.1% fall in glycosylated haemoglobin (HbA1c) is linked with a reduction in cardiovascular disease and other long-term end-points, it is important to facilitate every person with diabetes in their efforts to obtain better control of the condition.

## **Pump use in Ireland – current activity and future capacity**

Pump use is established in the United States, is growing rapidly in the UK, and is relatively in its infancy here. Around 100 people use pumps in Ireland at present, around 50 of whom were initiated in clinics here.

3 Dublin clinics have pump initiation programmes, St James, James Connolly Memorial Hospital and the Mater. The children's diabetes clinic at Our Lady's Hospital for Sick Children in Crumlin have considered pump therapy, but no cases have been initiated as yet.

In terms of potential, there are an estimated 15,000 people in Ireland with type 1 diabetes. Most pump users will be drawn from this population. While all insulin-requiring patients might benefit from pump therapy, the principal factor limiting initial conversion rates is a shortage of diabetes teams providing training in pump use.

Each patient requires intensive training and close supervision for an initial period of 6 weeks, and will take 3-6 months to become fully familiar with the device. This consumes a considerable amount of the team's time, specifically that of the diabetes nurse specialists. In the Mater clinic resources only allow initiation of 1 new patient each month. There is no indication at present that this will rise above 2 patients/month in 2002. St James have 6 patients currently on pumps, and 10 are awaiting training. They anticipate initiating 2 patients per month from November 2001. James Connolly Memorial Hospital have initiated around 2 patients in the past 6 months, and do not have plans to divert scarce professional time to a higher rate in the near future. They may reach 4 initiations in 2001, and 8-10 in 2002.

From this, I estimate that 26 patients will have been initiated during 2001, 56 in 2002 and 60 in 2003, probably including some children with diabetes.

### **Patient selection**

- Patients tend to self-select for pumps. They are exclusively patients with type 1 diabetes who are highly-motivated and have developed an expertise in their own condition.
- Most will have been using multiple dose injection therapy but have not achieved their desired level of control.
- Many have early complications such as retinopathy, nephropathy or large vessel disease, which contribute to the patient's personal motivation to take control of the condition. This is a motivator, not a criterion, as ideally intensive insulin therapy should aim to *prevent* complications.
- Patients make an important trade-off in accepting the long-term attachment to the pump in exchange for better control and a lower risk of complications. It is of considerable value and in the interest of healthcare equity, that they should not face a financial disincentive to adopt this method when offered it by their consultant.

## Cost issues

It is important to view the direct costs of pump therapy in the context of general diabetes expenditure. Recent research in Ireland has confirmed that we spend around IR£ 250 m annually on diabetes, but 60% of this is spent managing expensive and preventable complications, and only 18% on actual control of diabetes. There has been recognition by the Minister for Health and Children that diabetes care requires planning and investment, and this will be guided by initiatives such the St Vincent Task Group report, and the current Expert Review of Diabetes Services, to which this document will be appended.

Pumps are initially expensive, and they use consumables, but they reduce insulin costs by 1/3, and through correct implementation will prevent expensive complications. Pumps are currently supplied exclusively by Minimed, but other manufacturers sell systems in the UK and we can anticipate competitive market forces to impact on costs shortly.

### Approximate costs per patient:

Pump purchase	IR£ 2,700	€ 3428
Annual consumables	IR£ 1,600	€ 2032

### Direct savings:

Reduced insulin costs	30%	
Reduced consumables	IR£ 950	€ 1206

### Indirect savings:

Reduced clinical contact after initiation, as patients become self-reliant  
Reduced admissions for serious hypoglycaemia OR hyperglycaemia  
Reduced complications (MI, renal disease, visual impairment)

## **Recommendations**

1. As pump therapy is recommended by consultant endocrinologists to insulin-requiring patients on criteria of personal motivation more than clinical selection, and since the current initiation rate is very much limited by staffing resources, pump approval under the long-term illness scheme should be on the basis of consultant recommendation only, without additional clinical or means criteria being applied at present.
2. Further, considering the lengthy timescale involved in transfer and the need for teams to schedule their pump programme, prompt approval when a request has been made would facilitate the programme considerably for professionals and patients alike.
3. The medium-term cost-effectiveness of pump therapy implies that positive investment in staff numbers and training should be made to establish pump programmes where these do not already exist, and to increase capacity of those already established in regional diabetes centres.

## **Consultation process**

This document was produced in consultation with the following diabetes nurse specialists:

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**Dr Tony O'Sullivan**