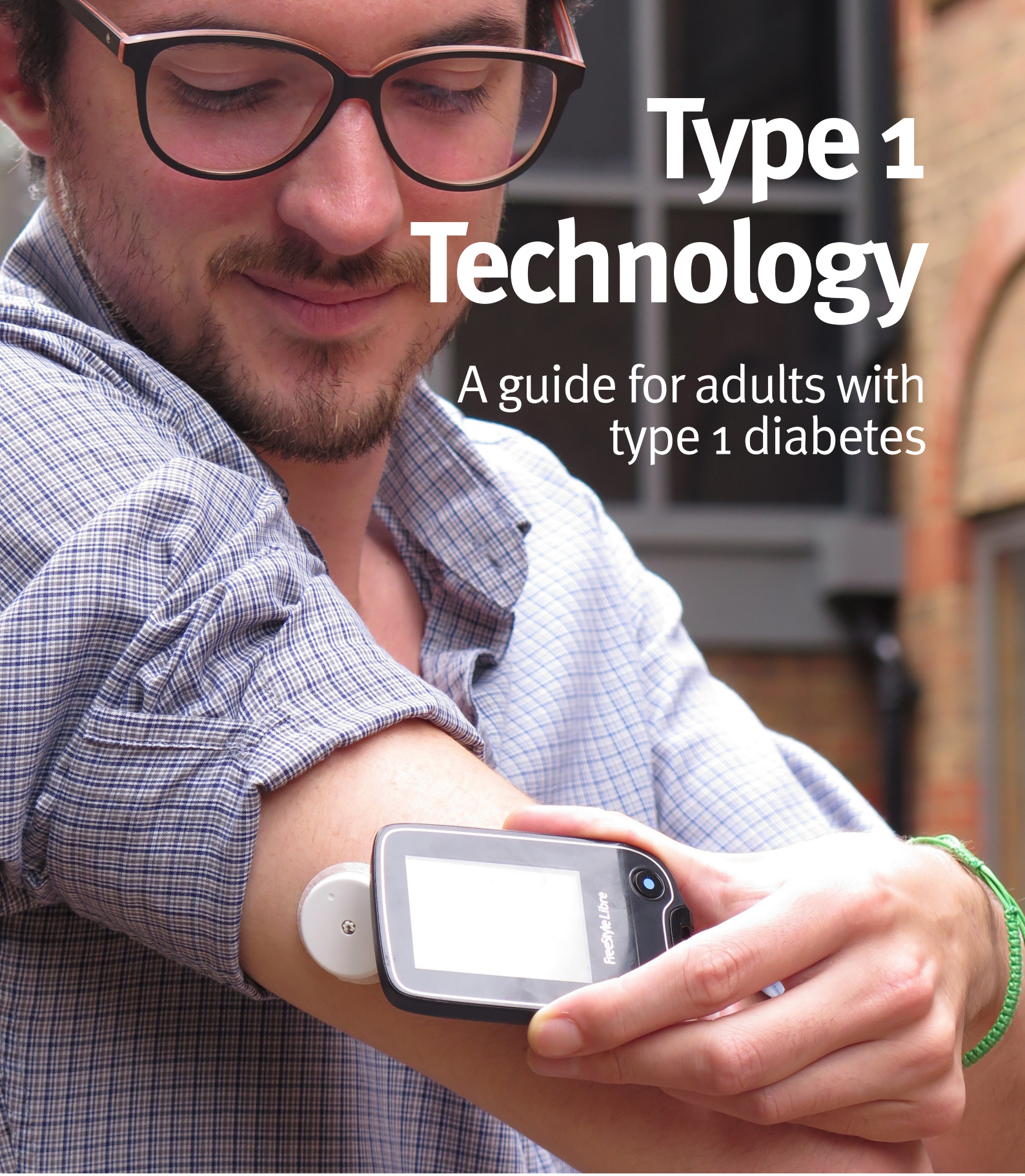

Type 1 Technology

A guide for adults with type 1 diabetes

DIABETES UK
CARE. CONNECT. CAMPAIGN.

INPUT
supporting your access to diabetes technology

JDRF
IMPROVING LIVES. CURING TYPE 1 DIABETES.

Contents

Introduction

This guide has been co-produced by Diabetes UK, INPUT Patient Advocacy and JDRF with input from NICE. It summarises new guidance from NICE on treatments and technology for adults with type 1 diabetes.

We hope this will be a useful tool when talking to your healthcare professionals about the technology you use to manage your diabetes (NG17, published August 2015).

NICE stands for the National Institute for Health and Care Excellence. NICE is an independent organisation, set up by the Government in 1999. It makes recommendations about how to best treat different health conditions, including diabetes. Its recommendations on diabetes are written by doctors, nurses and other healthcare professionals, and by people who have diabetes or care for someone with diabetes.

You can read the information NICE has written about type 1 diabetes for adults here. You can read the information NICE has written about access to insulin pumps here.

NICE guidance is developed for the NHS in England, and not all of it applies to other parts of the UK. You can see what NICE guidance applies in different parts of the UK here.

Different types of NICE guidance

NICE issues lots of different types of guidance. For type 1 diabetes, it has produced Clinical Guidelines, Technology Appraisals and Diagnostic Assessments. To see what different kinds of guidance NICE produces, see this page on the NICE website.

This guide is written to decode the new NICE Guidelines called 'Type 1 diabetes in adults: diagnosis and management' (NG17, published August 2015). NICE Clinical Guidelines set out the best possible care for people with the condition, and healthcare professionals in the NHS should follow these guidelines whenever possible. Technology Appraisals, such as 'TA151' covering insulin pumps, are different from Clinical Guidelines. Once a NICE Technology Appraisal recommends a treatment 'as an option', the NHS must make sure it is available within three months (unless otherwise specified) of the publication date.

Different strengths of recommendation

NICE's guideline recommendations vary in strength, based on how good the evidence there

is for how well a treatment works and how much it costs. The benefits and risks (for example side effects) of a treatment are also important. A NICE recommendation does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or carer.

The different strengths of NICE recommendations are set out below:

NICE wording	Definition
Must (must not)	NICE usually uses 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally NICE uses 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.
Should (offer / refer / advise)	NICE uses 'offer' (and similar words such as 'refer' or 'advise') when it is confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. NICE uses similar forms of words (for example, 'do not offer…') when it is confident that an intervention will not be of benefit for most patients.
Could (Consider)	NICE uses 'consider' when it is confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

1. Injections and pumps

Everyone with type 1 diabetes needs to take insulin. There are two main ways of taking insulin – through injections or through an insulin pump.

The guideline refers to a Technology Appraisal that has further recommendations.

Under the *Nice Guidelines: Type 1 Diabetes in Adults*, all adults with type 1 diabetes should be **offered** a basal-bolus insulin regime (also called a multiple daily injection or MDI regime) from the time of diagnosis. This involves taking a slow-acting 'basal' insulin once or twice a day; and a rapid-acting 'bolus' insulin with meals.

What does NICE say?

1.7.1

Offer multiple daily injection basal-bolus insulin regimes, rather than twice-daily mixed insulin regimens, as the insulin injection regime of choice for all adults with type 1 diabetes. Provide the person with guidance on using multiple daily injection basal-bolus insulin regimes.

1.7.6

For guidance on the use of continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes, see continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (NICE technology appraisal guidance 151).

Technology Appraisal 151 is guidance produced by NICE in 2008 on insulin pumps. The Technology Appraisal gives the specific reasons people should be given an insulin pump. If these reasons apply to you and your doctor believes an insulin pump is right for you, the NHS is legally required to provide you with one.

What does NICE say?

NICE technology appraisal guidance 151

Insulin pump therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:

- attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. For the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life

  or

- HbA1c levels have remained high (that is, at 8.5% [69 mmol/mol] or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

As well as referring to the technology appraisal, the *Nice Guidelines: Type 1 Diabetes in Adults* also states you should be **offered** insulin pump therapy as a strategy for managing impaired awareness of hypoglycaemia.

What does NICE say?

1.10.8

Review insulin regimens and doses and prioritise strategies to avoid hypoglycaemia in adults with type 1 diabetes with impaired awareness of hypoglycaemia, including:

- reinforcing the principles of structured education
- offering continuous subcutaneous insulin infusion (CSII or insulin pump) therapy
- offering real-time continuous glucose monitoring.

Note there are four other recommendations on strategies for managing hypo unawareness before this one.

The guideline recommends pump therapy as an option for adults with type 1 diabetes and gastroparesis (a chronic condition in which the stomach cannot empty itself in the normal way).

What does NICE say?

1.15.26

Consider continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes who have gastroparesis.

If you think the reasons in the technology appraisal apply to you but your clinic will not consider an insulin pump, has a waiting list longer than six months for a pump, or recommends a pump but cannot tell you how long it will take to provide it, you can contact INPUT for advice and support.

2. Appropriate length of injection needles

For people who take their insulin by injection, having the right length of injection needle can help to make injections less uncomfortable and ensure the insulin goes into the fat under the skin rather than into muscle.

Injecting insulin into muscle can make it difficult for your body to absorb the insulin properly, and can cause hypoglycaemia and visible bruising.

What does NICE say?

1.8.3

Offer needles of different lengths to adults with type 1 diabetes who are having problems such as pain, local skin reactions and injection site leakages.

The Forum for Injection Technique (a group of experienced UK diabetes specialist nurses) recommends that 4, 5 and 6mm needles are suitable for all people with diabetes, even if obese, and individuals using over 8mm needles should ensure they use a lifted skin fold to avoid injecting into muscle.

(http://fit4diabetes.com/files/2613/3102/3031/FIT_Recommendations_Document.pdf)

If you have been prescribed needles that could be too long, speak with the specialist nurse and ask them to write to your GP if they think the prescription should be changed.

3. Needle-free injection devices and injection ports

What does NICE say?

1.8.2

Provide adults with type 1 diabetes who have special visual or psychological needs with injection devices or needle-free systems that they can use independently for accurate dosing.

This allows the NHS to provide needle-free (or jet) injectors or three-day-wear injection ports if you have a specific need.

4. Blood glucose monitoring (choice of system and sufficient strips)

Blood glucose meters come in all shapes and sizes. A recent 'Meds & Kit' guide from Diabetes UK found 38 different blood glucose meters currently on the market.

What does NICE say?

1.6.16

Teach self monitoring skills at the time of diagnosis and initiation of insulin therapy.

1.6.17

When choosing blood glucose meters:

- Take the needs of the adult with type 1 diabetes into account.
- Ensure that meters meet current ISO (International Organization for Standardization) standards. [new 2015]

If you have been pushed into using a specific meter, mention to your GP that NICE states your needs should be taken into account and discuss the reasons why you would prefer a different system. This might include the need for a smaller meter, a bigger display, or compatibility with other technology for example.

The NICE guideline also recommends that adults with type 1 diabetes should perform at least four blood glucose tests per day, and potentially up to 10 or more depending upon personal circumstances and lifestyle:

What does NICE say?

1.6.10

Support adults with type 1 diabetes to test at least 4 times a day, and up to 10 times a day if any of the following apply...

The list of circumstances that may demand more frequent testing includes illness, pregnancy, sport, and experiencing more hypos.

These numbers should not be used by healthcare professionals or commissioners to limit test strips.

What does NICE say?

Enable additional blood glucose testing (more than 10 times a day) for adults with type 1 diabetes if this is necessary because of the person's lifestyle (for example, driving for a long period of time, undertaking high-risk activity or occupation, travel) or if the person has impaired awareness of hypoglycaemia.

If your GP will not provide enough test strips for you, ask your diabetes team to write to them and tell them how many strips should be prescribed.

5. Continuous Glucose Monitoring (CGM)

CGM systems measure your glucose levels every few minutes, so that you get a graph of glucose levels over time rather than just a single measurement. There are two main types of CGM: 'Real-time' CGM is a system that allows you to check your glucose levels at any time. CGM alarms can be set to let you know when your glucose levels go too high or too low. The other kind of CGM is 'retrospective', which let you look back at results by downloading results to a computer.

The NICE guideline recommends that CGM is not offered routinely to adults with type 1 diabetes (ie they do not recommend it for all adults with type 1 diabetes). However the are some criteria where it recommends CGM is **considered**.

What does NICE say?

1.6.22

Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- more than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycaemia.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
- Extreme fear of hypoglycaemia.
- Hyperglycaemia (HbA1c level of 75mmol/mol [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 1.6.11 and 1.6.12). Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.

1.6.24

Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes.

Typically, a 'severe' hypo is one that the person needs help from another person to treat or is one that needs treatment in a hospital. Be aware that 'accepting' help from another person is not the same as 'needing' help. Note that having more than one episode a year of severe hypoglycaemia will also mean you will have your driving licence revoked.

These recommendations mean that the NHS can provide funding for CGM if you meet the above criteria (and use MDI or a pump) but there is no obligation for that funding to be granted. You will also have to commit to using it at least 70 per cent of the time (three weeks per month). You will also need to have used standard self monitoring of blood glucose to their recommendations including frequency of testing (see page 5 of this guide).

The guideline recommends people with hypoglycaemia unawareness are **offered** CGM.

What does NICE say?

1.10.8

Review insulin regimens and doses and prioritise strategies to avoid hypoglycaemia in adults with type 1 diabetes with impaired awareness of hypoglycaemia including:

- offering real-time continuous glucose monitoring.

'Impaired awareness of hypoglycaemia' means the person cannot recognise that they are having a hypo until it becomes severe.

More background on CGM funding can be found here.

6. Flash Glucose Monitoring

Flash glucose monitoring is a new kind of glucose monitoring that is not covered by the NICE guideline. It was initially launched in the UK in September 2014, and at the time of writing (summer 2016) Abbott's Freestyle Libre is the only device of this kind. The Freestyle Libre has been very popular since launch.

To use the system, a Freestyle Libre sensor is inserted in the arm and worn for 14 days before being replaced. The user or their carer holds a handheld 'reader' very close to the sensor to 'scan' or 'flash' the sensor. The reader then shows a real-time glucose value with an arrow showing if blood glucose levels are going up or down, and a graph of glucose levels over the past eight hours. The Freestyle Libre reader includes a smart blood glucose meter that uses FreeStyle Optium test strips and blood ketone test strips. You can also use the Freestyle Libre without a meter if you have a near field communication-enabled phone.

Unlike CGM, flash glucose monitoring sensors do not continually send glucose measurements to the reader, so it will not alert the user or their carer to changes in glucose levels until the sensor is scanned with the reader.

Freestyle Libre is approved for use by people over the age of four. It is not currently funded by the NHS. NICE has not looked at how effective flash glucose monitoring is, and has made no recommendations on it.

7. Sensor-augmented pumps

Sensor-augmented pumps are insulin pumps that can receive readings from a CGM sensor. Some sensor-augmented pumps use CGM readings to adjust the user's insulin dose automatically, for example by reducing or stopping insulin delivery when the system predicts or detects a low glucose level. As of early 2016, the only sensor-augmented pumps available that automatically alter insulin dose based on CGM readings are the Veo and 640G, both made by Medtronic.

NICE Diagnostics Guidance 21, published in February 2016, recommended the Veo for managing blood glucose levels in people who experience frequent episodes of disabling hypoglycaemia despite 'optimal management with insulin pump therapy.' Diagnostics Guidance 21 did not assess the 640G. But it can be expected other sensor-augmented pumps will pass through the process.

What does NICE say?

1.1

The MiniMed Paradigm Veo system is recommended as an option for managing blood glucose levels in people with type 1 diabetes only if:

- they have episodes of disabling hypoglycaemia despite optimal management with continuous subcutaneous insulin infusion and
- the company arranges to collect, analyse and publish data on the use of the MiniMed Paradigm Veo system

1.3

People who start to use the MiniMed Paradigm Veo system should only continue to use it if they have a decrease in the number of hypoglycaemic episodes that is sustained. Appropriate targets for such improvements should be set.

Note also that if you are using sensor augmented pump systems for reasons other than those recommended in this guidance, then the guidance states you should be able to continue using them. However NICE's Diagnostics Guidance is different to its Technology Appraisals, and the NHS is not legally required to follow them.

If you think that you fit the criteria and could benefit from using the Veo, print out the relevant page from the Diagnostics Assessment for discussion with your diabetes care team.

8. Blood ketone monitoring

It is important for people with type 1 diabetes to check their ketone levels when their glucose levels are very high or they are unwell. Like a blood glucose meter, a blood ketone meter gives a real-time result, compared to urine testing, which can only show the glucose levels that were in the blood a few hours ago. Checking blood rather than urine ketones and acting quickly to reduce them can help prevent hospital admission for diabetic ketoacidosis (DKA), a potentially life-threatening complication of diabetes.

NICE guidelines recommend in particular that women with with type 1 diabetes who are planning pregnancy should be **offered** a blood ketone meter and blood ketone test strips, and be advised how and when to use them (note that JDRF's Pregnancy Toolkit is a further resource for women with type 1 diabetes planning pregnancy).

What does NICE say?

1.1.15

Offer women with type 1 diabetes who are planning to become pregnant blood ketone testing strips and a meter, and advise them to test for ketonaemia if they become hyperglycaemic or unwell {new 2015]

NICE guidance also states all adults should be considered for either blood or urine ketone testing tools.

What does NICE say?

1.11.1

Consider ketone monitoring (blood or urine) as part of 'sick-day rules' for adults with type 1 diabetes, to facilitate self-management of an episode of hyperglycaemia [new 2015]

Your diabetes clinic is unlikely to object to the need for a blood ketone meter. If the GP will not provide blood ketone test strips because of their cost, ask your diabetes team to write to your GP and request the prescription.

9. Intraperitoneal ports

An intraperitoneal port is surgically implanted through the abdominal wall allowing a regular external insulin pump to deliver insulin into the peritoneal cavity. There is currently only one brand available - DiaPort by Roche.

This is a very niche therapy - at the time of writing this guide there are only five people with an intraperitoneal port in the UK. A consensus guideline to the indication for its use is being written by specialist clinicians in the UK and will be published by INPUT when it is available.

NICE has not appraised it or mentioned it in this guidance. It will need to be funded by IFR (individual funding request) presented to your local area IFR panel by a tertiary specialist clinic. At the time of writing this guide there are three intraperitoneal port centres in the UK.

For more information please visit INPUT's website.

Further information and support

If you experience difficulty accessing any technologies described in this guide in accordance with the NICE Clinical Guideline or Technology Appraisal, you can contact INPUT, the charity supporting patients' access to diabetes education and technology, for more information and assistance.

www.inputdiabetes.org.uk

[or 0800 228 9977 (answerphone) if you do not have Internet access]

JDRF is the type 1 diabetes charity, improving lives until we find the cure. We fund research to cure, treat and prevent type 1 diabetes including a major initiative to perfect the artificial pancreas, a technology that could revolutionise treatment of type 1 diabetes.

www.jdrf.org.uk

Diabetes UK is the leading charity that cares for, connects with and campaigns on behalf of every person affected by or at risk of diabetes.

www.diabetes.org.uk