Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	7th June 2022 (updated to include type 2 diabetes)
Appraisal & Details	The Northern (NHS) Treatment Advisory Group considered an appraisal of **i-Port Advance® for use in children and adults with Type 1 and Type 2 diabetes**

Recommendation	**The Northern (NHS) Treatment Advisory Group recommends the use of i-Port Advance® for use in children and adults with Type 1 diabetes as recommended by specialists for patients that fulfil the following criteria:**
	• **Children or adults with Type 1 diabetes**
	• **As an alternative option in the following groups of patients who would otherwise meet the NICE criteria for insulin pump therapy**
	  ○ **Patients in whom multiple daily injections are impractical and inappropriate where use of an injection port may avoid the need to move to insulin pump therapy**
	  ○ **Patients with significant anxiety and needle phobia who are avoiding or missing injections**
	  ○ **Patients with a raised HbA1C > 69mmol /l with poor compliance with treatment or who are injecting into lipohypertrophy despite support and advice to avoid these areas.**
	• **Continued use of i-Port Advance® device to be reviewed every 3-6 months.**
	
	NTAG noted that use of i-Port Advance® device in these groups of patients may offer a cost saving in delaying the progression to insulin pump therapy and therefore may offer an alternative option to pump therapy in such patients.
	
	NICE TA151(July 2018) Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus recommends the following:
	
	• Continuous subcutaneous insulin infusion (CSII or '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.
	• CSII therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:
	  ○ MDI therapy is considered to be impractical or inappropriate, and

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	○ children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years. **The Northern (NHS) Treatment Advisory Group recommends the use of i-Port Advance® for use in children and adults with Type 2 diabetes as recommended by specialists for patients that fulfil the following criteria:** • **Patients on more than one injection of insulin a day rather than an MDI/basal bolus regimen.** • **Patients in whom multiple daily injections are impractical and inappropriate and where use of an injection port may improve glycaemic control.** • **Patients with significant anxiety and needle phobia who are avoiding or missing injections.** • **Patients with a raised HbA1C > 69mmol /l with poor compliance with treatment or who are injecting into lipohypertrophy despite support and advice to avoid these areas.** • **Continued use of i-Port Advance® device to be reviewed every 3-6 months** **This is subject to an audit of use in 12 months to show compliance with these criteria and evidence of positive outcomes.** NTAG noted that use of i-Port Advance® device in these groups of Type 2 diabetes patients may offer a cost saving in terms of improved glycaemic control and reduction in micro-vascular complications and addition drug therapies e.g. retinopathy and laser, painful neuropathy requiring other oral agents (duloxetine/gabapentin). Note patients with Type 2 diabetes are not eligible for insulin pump therapy. It is recommended that an ongoing audit of the of i-Port Advance® device is carried out to inform the evidence base for the use of device and demonstrate how long use of the device delays the progression to insulin pump therapy.
Clinical evidence summary	Clinical evidence for the use of i-Port Advance® device is limited. However, based on problems associated with insulin administration by injection(s), such as pain, anxiety (needle phobia), lipohypertrophy, and risk of infection, there may be some degree of acceptability for the device which may assist in achieving optimal glycaemic control reducing admissions from diabetic ketoacidosis (DKA) and reducing the insulin doses required. A literature search in February 2022 by the RDTC has found no new published clinical evidence regards to the use of i-Port Advance® in type 2 diabetes patients. There have been three new papers published since the NTAG report in February 2019 which discuss its use in type 1 diabetes patients. No NICE guidance or appraisal of the i-PORT® device is currently available.

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Safety	Incorrect medication absorption, infection, or site irritation may result from improper application to the body or maintenance of the i-Port Advance® injection port insertion site, or both. If the insertion site becomes irritated or inflamed, remove and discard the device and apply a new device to a different location on the body.
Patient Perspective	Although, evidence highlighting benefits if i-Port Advance® device is lacking, problems associated with insulin administration by injection such as pain, anxiety and risk of infection may point towards applicability of the i-Port Advance® device. This in turn may result in clear therapeutic benefit (i.e. helping to achieve optimal glycaemic control) within currently diagnosed patients on insulin therapy. The i-Port Advance® device can be worn during swimming, bathing, sleeping. It also does not interfere with daily activities.
Cost analysis summary	The i-Port Advance® device is not currently listed in the Drug Tariff. It can be obtained directly from Medtronic UK.18 A box of 10 i-PORT Advance devices which, based on a 72 hour expiry is expected to last up to a month costs £72.00 ex VAT.
Financial impact **PbR: NA**	Based on the expected expiry and usage of i-Port Advance® device, the annual cost per patient is expected to be around £870. There may be potential cost savings associated with the use of the i-Port Advance® device as it may delay progression to use insulin pump therapy in Type 1 diabetes. Number of Children and young people with type 2 diabetes on insulin is estimated to be 0-5 in the NENC. Number of adults with type 2 diabetes meeting the criteria for i-Port is estimated to be 5-10 in the NENC.