NICE National Institute for Health and Care Excellence

NICE guidance

Allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus

HealthTech guidance

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www.nice.org.uk/guidance/htg165

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance 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 guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guidance replaces IPG257 and IPG13.

1 Recommendations

This document together with the HealthTech guidance published on autologous pancreatic islet cell transplantation for improved glycaemic control after pancreatectomy replaces previous guidance IPG13 on pancreatic islet cell transplantation.

1.1 The evidence on allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus shows short-term efficacy with some evidence of long-term efficacy. The evidence on safety shows that serious complications may occur as a result of the procedure. The long-term immunosuppression required is also associated with a risk of adverse events. In units with established experience in allogeneic pancreatic islet cell transplantation, the procedure may be used with normal arrangements for clinical governance (see also section 2.5.2).

1.2 During consent, clinicians should ensure that patients understand the potential complications of the procedure and the uncertainty about its efficacy in the long term. They should provide patients with clear, written information. In addition, use of NICE's information for the public is recommended.

1.3 Patient selection for this procedure should involve a multidisciplinary team. Selection criteria should take into account that the procedure is particularly indicated for patients with hypoglycaemia unawareness and/or those already on immunosuppressive therapy because of renal transplantation.

1.4 Further audit and research should address the effect of the procedure on quality of life and its long-term efficacy, particularly in relation to the complications of diabetes (see section 3.1).

2 The procedure

2.1 Indications and current treatments

2.1.1 Type 1 diabetes mellitus is caused by insufficient insulin secretion and is treated with exogenous insulin. This may result in hypoglycaemic episodes, which are usually easily recognised and treated. In a few people, hypoglycaemia occurs without warning ('hypoglycaemia unawareness'), with life-threatening consequences.

2.2 Outline of the procedure

2.2.1 Islet cells are obtained from pancreata of brain-dead donors (two are often required). The patient is started on immunosuppressive therapy, which continues for the long term. Under local anaesthesia (sometimes with sedation) and using imaging guidance, a catheter is inserted percutaneously into the portal vein and the grafted islet cells infused into the liver. More than one infusion may be required.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, see the overview.

2.3 Efficacy

2.3.1 A registry study of 112 patients reported that a severe hypoglycaemic episode was experienced by 5% in the year following transplantation compared with 82% in the year prior to transplantation (numbers not reported). In a case series of 36 patients, there were no hypoglycaemic episodes among patients with residual graft function during follow-ups of 1 to 12 months. A case series of 65 patients reported significantly reduced hypoglycaemia unawareness and improved diabetic control compared with baseline for up to 4 years after transplantation (numbers not reported).

2.3.2 In the registry study of 112 patients, 67% and 58% were insulin independent at 6 months and 1 year after transplantation, respectively (numbers not reported). For patients who remained insulin dependent, insulin requirements were reduced by a mean of 57% from baseline at 6 months and 69% at 1 year. In this study, 13% (15 out of 112) of patients had complete graft failure. In the case series of 36 patients, 58% (21 out of 36) achieved insulin independence during a median follow-up of 41 months. However, 76% (16 out of 21) were insulin dependent again after 2 years.

2.3.3 A non-randomised controlled trial of 99 patients who had the procedure reported that fear of hypoglycaemic episodes as measured by the 'Hypoglycaemia fear survey' improved significantly following the first infusion of islet cells ($p<0.00001$).

2.3.4 The Specialist Advisers considered key efficacy outcomes to include reduction in hypoglycaemic episodes, improved glycaemic control, normalised C-peptide levels (indicating graft function) and insulin independence.

2.4 Safety

2.4.1 Two case series of 65 and 51 patients reported procedure-related intraperitoneal bleeding in 23% (15 out of 65), and 8% (4 out of 51; 7 haemorrhage episodes) of patients. A case series of 36 patients reported intraperitoneal bleeding during 9% (7 out of 77) of infusions. Portal (or branch) vein thrombosis was reported in 8% (5 out of 65), 4% (2 out of 51) and 3% (2 out of 36) of patients, and gall bladder puncture requiring laparotomy in 3% (2 out of 65, and 1 out of 36) of patients.

2.4.2 In the registry study of 112 patients, 77 serious adverse events were reported; 22% (17 out of 77) were life-threatening and 58% (45 out of 77) required hospitalisation. Overall, 95% (73 out of 77) of adverse events resolved without residual effects. The authors judged that 17% of all adverse events were related to the infusion procedure and 27% to immunosuppression (numbers not reported).

2.4.3 A case report described a patient who died of West Nile virus encephalitis – a potential infection in immunosuppressed patients.

2.4.4 The Specialist Advisers considered theoretical adverse events to include haemorrhage, portal vein thrombosis, portal hypertension, immunosuppression-related complications and transmission of donor material containing infectious agents or neoplastic cells.

2.5 Other comments

2.5.1 The Committee noted that immunosuppressive regimens and technology for harvesting islet cells continue to evolve.

2.5.2 The Committee noted that the National Commissioning Group (NCG), which has a remit to commission highly specialised national services for very rare conditions or treatments for the population of England, has developed service standards for pancreatic islet cell transplantation that are used as the basis for designation and commissioning of these services. Scottish residents also have access to the service under an agreement between the NCG and the National Services Division, Scotland. Health Commission Wales has a separate agreement with the provider for Welsh residents. The Regional Medical Services Consortium (RMSC) commissions specialist regional services for the population of Northern Ireland. The RMSC will commission outside the region, on an individual basis, in cases for which services are not available in Northern Ireland.

3 Further information

3.1 This guidance requires that clinicians or units undertaking the procedure for the first time make special arrangements for audit. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

3.2 NICE has issued guidelines on type 1 diabetes in adults, diabetes (type 1 and type 2) in children and young people and diabetic foot problems. NICE has also issued technology appraisal guidance on continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE has published HealthTech guidance on autologous pancreatic islet cell transplantation for improved glycaemic control after pancreatectomy.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 257 has been migrated to HealthTech guidance 165. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.