



EFFECTIVE DATE: 06|01|2006
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OVERVIEW

This policy documents the coverage criteria for Islet Cell Transplants. Autologous islet transplantation, performed in conjunction with pancreatectomy, is proposed to reduce the likelihood of insulin dependent diabetes. Moreover, allogeneic islet cell transplantation is being investigated as a treatment or cure for patients with type 1 diabetes.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Autologous Islet Transplantaton:

BlueCHiP for Medicare and Commercial Products

Autologous pancreas islet transplantation is considered medically necessary as an adjunct to a total or near total pancreatectomy in members with chronic pancreatitis. Islet transplantation is considered not medically necessary in all other situations as the evidence is insufficient to determine the effects of the technology on health outcomes.

Allogeneic Islet Transplantation:

BlueCHiP for Medicare

Allogeneic Pancreatic islet cell transplantation is covered for BlueCHiP for Medicare members only as part of an approved clinical trial. Refer to Related Policy section.

Commercial Products

Allogeneic islet transplantation is considered not covered for the treatment of type 1 diabetes as there is no FDA approval for this indication.

COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, for applicable not medically necessary/transplant surgery/experimental/investigational benefits/coverage.

BACKGROUND

Pancreatectomy is utilized in the treatment of patients with chronic pancreatitis. Autologous islet transplantation, performed in conjunction with pancreatectomy, is proposed for chronic pancreatitis patients. Allogeneic islet transplantation is proposed for selected patients with type 1 diabetes. In autologous islet transplantation, during the pancreatectomy procedure, islet cells are isolated from the resected pancreas using enzymes, and a suspension of the cells is injected into the portal vein of the patient's liver. Once implanted, the beta cells in these islets begin to make and release insulin. In the case of allogeneic islet cell transplantation, cells are harvested from the deceased donor's pancreas, processed, and injected into the recipient's portal vein.

Up to 3 donor pancreas transplants may be required to achieve insulin independence. Allogeneic transplantation may be performed in the radiology department.

Chronic Pancreatitis

Primary risk factors for chronic pancreatitis include toxic-metabolic, idiopathic, genetic, autoimmune, recurrent and severe acute pancreatitis, or obstructive (the TIGAR-O classification system). Patients with chronic pancreatitis may experience intractable pain that can only be relieved with a total or near total pancreatectomy. However, the pain relief must be balanced against the certainty that the patient will be rendered an insulin-dependent diabetic.

Type 1 Diabetes

Allogeneic islet transplantation has been used for type 1 diabetes to restore normoglycemia and, ultimately, reduce or eliminate the long-term complications of diabetes such as retinopathy, neuropathy, nephropathy, and cardiovascular disease. Islet transplantation potentially offers an alternative to whole-organ pancreas transplantation. However, a limitation of islet transplantation is that 2 or more donor organs are usually required for successful transplantation, although experimentation with single-donor transplantation is occurring. A pancreas that is rejected for whole-organ transplant is typically used for islet transplantation. Therefore, islet transplantation has generally been reserved for patients with frequent and severe metabolic complications who have consistently failed to achieve control with insulin-based management.

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Islet cells are included in these regulations.

For individuals with chronic pancreatitis who receive autologous pancreas islet transplantation, the evidence includes case series and systematic reviews. Relevant outcomes are overall survival, change in disease status, medication use and treatment-related morbidity. Autologous islet transplants are performed in the context of total or near total pancreatectomies to treat intractable pain for chronic pancreatitis. The procedure appears to significantly decrease the incidence of diabetes after total or near total pancreatectomy in patients with chronic pancreatitis. In addition, this procedure is not associated with serious complications itself and is performed in patients who are already undergoing a pancreatectomy procedure. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with type 1 diabetes who receive allogeneic pancreas islet transplantation, the evidence includes case series and systematic reviews. Relevant outcomes are overall survival, change in disease status, medication use and treatment-related morbidity. A wide range of insulin independence has been reported from case series. There is conflicting evidence for allogeneic islet transplantation in reducing long-term diabetic complications. Long-term comparative studies are required to determine the effects of allogeneic islet transplantation in type 1 diabetics. The evidence is insufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Guidance from the National Institute for Clinical Excellence (NICE), published in 2008, states that the evidence on allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus shows short-term efficacy with some evidence of long-term efficacy. Evidence on safety shows that serious complications may occur, and the long-term immunosuppression required is also associated with risk of adverse events. The procedure is particularly indicated for patients with hypoglycemia unawareness or those already on immunosuppressive therapy because of renal transplantation. A 2008 update of guidance on autologous islet cell transplantation for improved glycemic control after pancreatectomy states that studies show some short-term efficacy, although most patients require insulin therapy in the long term. Complications mainly result from the major surgery involved in pancreatectomy rather than from the islet cell transplantation.

Effective October 1, 2004, Medicare will cover pancreatic islet transplantation in patients with type 1 diabetes participating in the context of a clinical trial sponsored by the National Institutes of Health. Partial pancreatic

tissue transplantation or islet transplantation performed outside the context of a clinical trial will continue to not be covered.

CODING

BlueCHiP for Medicare and Commercial Products

The following code is covered with a diagnosis of chronic pancreatitis:

48160 Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells

The following code is reported for pancreatic islet cell transplantation and laparoscopy:

48999 Unlisted procedure, pancreas

ICD-10 Diagnosis Code

K86.1 Other Chronic Pancreatitis

RELATED POLICIES

Clinical Trials BlueCHiP for Medicare

BlueCHiP for Medicare National and Local Coverage Determinations

PUBLISHED

Provider Update, November 2017

Provider Update, January 2017

Provider Update, November, 2014

Provider Update, April, 2015

Provider Update, September 2013

Provider Update, September 2012

Provider Update, September 2011

Provider Update, December 2010

Provider Update, July 2009

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