

Corporate Medical Policy

Islet Cell Transplantation

File Name:	islet_cell_transplantation
Origination:	10/2001
Last CAP Review:	7/2011
Next CAP Review:	7/2012
Last Review:	7/2011

Description of Procedure or Service

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.

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. The pain relief must be balanced against the certainty that the patient will become an insulin dependent diabetic if a pancreatectomy is performed. Autologous islet cell transplantation has been investigated as a technique to prevent this from occurring. Allogeneic islet transplantation has been used for type 1 diabetes to restore normoglycemia and, ultimately, reduce the long-term complications of diabetes such as retinopathy, neuropathy, nephropathy, and cardiovascular disease. Islet transplantation 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. Islet transplantation is recommended only for those with frequent and severe metabolic complications who have consistently failed to achieve control with insulin-based management.

Islet cells are regulated by the U.S. Food and Drug Administration (FDA) which classifies allogeneic islet cell transplantation as somatic cell therapy, requiring premarket approval. Islet cells also meet the definition of a drug. Clinical studies to determine the safety and effectiveness outcomes of allogeneic islet transplantation must be conducted under FDA investigational new drug (IND) regulation. While at least 35 INC applications have been submitted to the FDA, no center has submitted a biologics license application.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Autologous Islet Cell Transplantation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Allogeneic islet transplantation is considered investigational for the treatment of type 1 diabetes. BCBSNC does not provide coverage for investigational services or procedures.

Islet Cell Transplantation

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Islet Cell Transplantation is covered

Autologous pancreas islet cell transplantation may be considered medically necessary when performed together with a total or near total pancreatectomy in patients with chronic pancreatitis.

When Islet Cell Transplantation is not covered

When the criteria listed above are not met.

Allogeneic islet transplantation is considered investigational for the treatment of type 1 diabetes.

Policy Guidelines

Although the published experience with autologous islet cell transplantation is limited, 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 as an adjunct to the pancreatectomy procedure.

The 2009 update from the Collaborative Islet Transplant Registry (CIRT) which collects and monitors data on allogeneic islet transplantation includes information from 27 North American, three European, and two Australian centers. Combining all data, the report describes 412 islet transplant recipients. Of these recipients, most (84%) received islet-alone infusions (IA), while the others (16%) had previously received a kidney transplant and are designated islet-after-kidney (IAK) recipients. About one quarter received only one infusion, half received two islet infusions from separate donors, a quarter received three infusions, while a very small number received four infusions (2%). The majority of recipients (88%) were placed on immunosuppression regimens. Overall, 70% of all recipients achieved insulin independence (defined as 14 or more consecutive days without insulin). While the remainder remained on insulin, their daily requirements decreased substantially. The likelihood of achieving insulin independence increases as more infusions are given. However, over time there is a steady decline in the maintenance of insulin independence. Of those who ever achieved insulin independence, 70% retained this status one year after achieving it and 55% remained insulin independent after two years.

With the expansion of clinical trials, the number of new allogeneic islet cell recipients will continue to rise. The current data suggests that the best candidates for islet transplantation are those with better glycemic control to start with. Close relationships between procurement, processing, and transplant teams are associated with favorable outcomes. However, more extensive follow-up is needed to evaluate the long-term safety of allogeneic islet transplantation and its impact on complications of diabetes mellitus. Thus, while the techniques for allogeneic islet cell transplants are evolving, the impact on net health outcomes is still uncertain.

Billing/Coding/Physician Documentation Information

Islet Cell Transplantation

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 48160, G0341, G0342, G0343, S2102

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual 7.03.12, 8/15/2001

Specialty Matched Consultant Advisory Panel - 7/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.12, 4/29/2003.
Specialty Matched Consultant Advisory Panel - 6/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.12, 12/14/2005.

Collaborative Islet Transplant Registry (CITR). 2005 Annual report. Sponsored by the National Institute of Diabetes & Digestive & Kidney Diseases, NIH. Retrieved 3/24/06 from <http://spitfire.emmes.com/study/isl/reports/CITR%202nd%20Annual%20Data%20Report%201%20uly%202005.pdf>

Specialty Matched Consultant Advisory Panel - 5/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.12, 12/14/08

Specialty Matched Consultant Advisory Panel - 5/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.12, 6/10/10

Alejandro R, Barron FB, Hering BJ and Wease S. 2008 Update from the Collaborative Islet Transplant Registry Transplantation. 2008 Dec 27;86(12):1783-8.

Collaborative Islet Transplant Registry (CITR). Sixth annual report. (Nov. 2009). Retrieved on July 26, 2010 from <http://citregistry.org/>

Aguayo-Mazzucato C, Bonner-Weir S. Stem cell therapy for type 1 diabetes mellitus. Nat Rev Endocrinol 2010; 6(3):139-48.

de Vos P, Spasojevic M, Faas MM. Treatment of diabetes with encapsulated islets. Adv Exp Med Biol 2010; 670:38-53.

Specialty Matched Consultant Advisory Panel 8/2010

National Institute for Health and Clinical Excellence (NICE). Autologous pancreatic islet cell transplantation for improved glycaemic control after pancreatectomy. September 2008. Accessed June 2011 at <http://www.nice.org.uk/Guidance/IPG274>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.03.12, 6/9/2011

Islet Cell Transplantation

Policy Implementation/Update Information

10/01	Original policy issued.
8/02	Specialty Matched Consultant Advisory Panel review 7/1/2002. No criteria changes. Format changes.
6/24/04	Specialty Matched Consultant Advisory Panel review. No changes to criteria. Benefit Application and Billing/Coding section updated for consistency. Added CPT code 48160 which is specific to this policy and removed 48146. References added.
10/14/04	Codes G0341, G0342 and G0343 added to the Billing/Coding section.
6/19/06	Specialty Matched Consultant Advisory Panel review 5/18/2006. Name changed from "Islet Cell Transplantation, Autologous" to "Islet Transplantation". Information added to "Description of Procedure or Service" section related to allogeneic use and FDA regulation. Additional policy statement added to indicate "Allogeneic islet transplantation is considered investigational for the treatment of type 1 diabetes. Statement added to "When Not Covered" section also. Rationale added to "Policy Guidelines" section. CPT codes 0141T, 0142T, 0143T and HCPCS code S2102 added to "Billing/Coding" section. References added.
6/30/08	Specialty Matched Consultant Advisory Panel review 5/29/08. No change to policy statement. References added. (btw)
6/22/10	Policy Number(s) removed (amw)
9/28/10	Specialty Matched Consultant Advisory Panel review 8/2010. Updated references. Updated Policy Guidelines. (mco)
8/30/11	Description section and Policy Guidelines section updated. No change in medical coverage criteria. Specialty Matched Consultant Advisory Panel review 7/27/11. Policy accepted as written. (adn)
1/1/12	Coding update. CPT Codes 0141T, 0142T, 0143T deleted. (adn)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.