Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.

Category: Surgery
***Current Policy Effective Date: 11/1/08**

Title: Autologous Islet Cell Transplantation for Pancreatitis

Procedure Code(s): 48160

Description / Background

Pancreatitis is an inflammatory disease which may cause intractable and progressively irreversible pain. Total pancreatectomy is used for the treatment of chronic pancreatitis which renders the patient an insulin dependent diabetic. High rates of postoperative deaths and complications have been associated with this procedure. Autologous islet cell transplantation may be used in an attempt to establish normoglycemia and phasic insulin secretion in order to achieve prolonged exogenous insulin independence. The islets of Langerhans are isolated from a resected pancreas and emulsified in balanced salt solution and collagenase. This emulsified pancreatic tissue is then infused over 30 to 60 minutes into the portal vein via a tributary (omental vein) using a mesenteric vein catheter, which is operatively placed after systemic heparinization.

CPT / HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion
0141T	Pancreatic islet cell transplantation through portal vein, percutaneous
0142T	Pancreatic islet cell transplantation through portal vein, open

BCBSM/BCN Medical Policies are developed to provide general information about Blue Cross Blue Shield and Blue Care Network of Michigan medical policies. This policy is not intended to offer coverage or medical advice. This policy may be updated and is therefore subject to change.

0143T Laparoscopy, surgical, pancreatic islet cell transplantation through portal vein

Other codes (investigational, not medically necessary, etc.):
N/A

Diagnoses / Medical Conditions

Chronic pancreatitis

Medical Policy Statement

The safety and effectiveness of autologous islet cell transplantation after a total or near total pancreatectomy in patients with pancreatitis have been established. It may be considered a useful therapeutic option when indicated.

Rationale

Autologous islet cell transplantation has been investigated for many years. Although the number of patients in studies has been small and published experience limited, there have been no reports of significant morbidity or mortality associated with this procedure. This procedure is not associated with serious complications itself and is performed as an adjunct to the pancreatectomy procedure.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

Pancreatitis is an inflammation of the pancreas which may cause severe pain, nausea and vomiting. The only relief from this pain may be the removal of the pancreas. The islets of Langerhans within the pancreas produce insulin. With the removal of the pancreas it is a certainty that the patient will become an insulin-dependent diabetic. During the removal of the pancreas these islets are removed and reinserted into the portal vein of the liver where they can function to produce insulin. It has been established that autologous transplant of these islets is safe and effective and may prevent the patient from becoming an insulin-dependent diabetic.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Criteria for a pancreatectomy with islet cell autotransplant include but are not limited to the following:

- Patients who need total pancreatectomy or partial pancreatectomy when a completion pancreatectomy might be required in the future.
- Non-diabetic at the time of pancreatectomy or if diabetic, mild diabetes with c-peptide present as an indication of beta cell function.

BCBSM/BCN Medical Policies are developed to provide general information about Blue Cross Blue Shield and Blue Care Network of Michigan medical policies. This policy is not intended to offer coverage or medical advice. This policy may be updated and is therefore subject to change.

- Patients with pancreatitis, or benign disease of the pancreas.

Exclusion:
Cancer of the pancreas.

Related Policies

- Pancreas Transplant
- Allogeneic Islet Cell Transplantation for Type I Diabetes

Medicare Information

NCD for Pancreas Transplants (260.3) Effective Date of this Version, 4/26/2006
Medicare also excludes coverage of transplantation of partial pancreatic tissue or islet cells. Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial), is not covered. (See section 260.3.1 of the NCD Manual).

NCD for Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1), Effective Date of this Version, 10/1/2004
"Specifically, Medicare will cover transplantation of pancreatic islet cells; the insulin producing cells of the pancreas, for type I diabetes. Coverage will include the costs of acquisition and delivery of the pancreatic islet cells, as well as clinically necessary inpatient and outpatient medical care and immunosuppressants."

"Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial continues to be non-covered."

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

References

- Blondet, Juan J., MD, et al., "The Role of Total Pancreatectomy and Islet Autotransplantation for Chronic Pancreatitis," *Surgical Clinics of North America*, Vol. 87, 2007, pp. 1477-1501.
- Blue Cross Blue Shield Association, "Islet Cell Transplantation," *Medical Policy Reference Manual*, Issue 4:2004, Original Policy Date 8/15/01, Last Review Date 2/14/08.
- Camilleri, Michael, MD, "Diabetic Gastroparesis," *The New England Journal of Medicine*," Vol. 356, No. 8, 2007, pp. 820-829.
- Centers for Medicare and Medicaid Services (CMS), "NCD for Pancreas Transplants (260.3)," *Medicare Coverage Database*, Effective Date of this Version 10/1/2004.

BCBSM/BCN Medical Policies are developed to provide general information about Blue Cross Blue Shield and Blue Care Network of Michigan medical policies. This policy is not intended to offer coverage or medical advice. This policy may be updated and is therefore subject to change.

- *Hayes Medical Technology Directory*, "Pancreas-After-Kidney Transplantation (PAK)," (PANC1202.22), Lansdale, PA, Hayes, Inc., February 1999, Update 9/9/04, Archived 2006.
- Watkins, J. G., MD, et al., "Pancreatic Autotransplantation in Chronic Pancreatitis," *World Journal of Surgery*, Vol. 27, 2003, pp. 1235-1240.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 11, 2008, the date the research was completed.

BCBSM/BCN Medical Policies are developed to provide general information about Blue Cross Blue Shield and Blue Care Network of Michigan medical policies. This policy is not intended to offer coverage or medical advice. This policy may be updated and is therefore subject to change.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
2/11/03	2/11/03	2/11/03	Joint medical policy established
3/19/04	3/19/04	3/26/04	Routine maintenance
6/25/05	6/25/05	6/30/05	Maintenance with policy statement change
11/1/06	8/28/06	10/29/06	Routine maintenance
11/1/07	8/21/07	10/22/07	Routine maintenance
11/1/08	8/19/08	10/28/08	Routine maintenance

Next Review: This is an established policy and no longer subject to routine review.

Pre-Consolidation Medical Policy History

Original Policy Date		Comments
BCN	N/A	Revised: N/A
BCBSM	12/20/99	Revised: N/A

BCBSM/BCN Medical Policies are developed to provide general information about Blue Cross Blue Shield and Blue Care Network of Michigan medical policies. This policy is not intended to offer coverage or medical advice. This policy may be updated and is therefore subject to change.

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ISLET CELL TRANSPLANTATION FOR PANCREATITIS

I. Short Description

Pancreatitis is an inflammation of the pancreas which may cause severe pain, nausea and vomiting. The only relief from this pain may be the removal of the pancreas. The islets of Langerhans within the pancreas produce insulin. With the removal of the pancreas it is a certainty that the patient will become an insulin-dependent diabetic. During the removal of the pancreas these islets are removed and reinserted into the portal vein of the liver where they can function to produce insulin. It has been established that autologous transplant of these islets is safe and effective and may prevent the patient from becoming an insulin-dependent diabetic.

II. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered
BCNA (Medicare Advantage)	Covered only in the context of a clinical trial
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service. *Exception: If BCN65 member has an "exact-fill" option, BCN may cover the service even if Medicare does not.*
BlueCaid	Covered only in the context of a clinical trial

III. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.
- Appropriate copayments will apply. Refer to certificate section, "**Organ and Tissue Transplants**" and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.

IV. Effective Dates:

Policy updated: 6/30/05, 3/19/04, 6/25/05, 11/1/06, 11/1/07, 11/1/08
Joint policy effective date: 2/11/03

BCBSM/BCN Medical Policies are developed to provide general information about Blue Cross Blue Shield and Blue Care Network of Michigan medical policies. This policy is not intended to offer coverage or medical advice. This policy may be updated and is therefore subject to change.