EFFECTIVE DATE: 06/01/2006
POLICY LAST UPDATED: 09/02/2014

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.

PRIOR AUTHORIZATION

Prior Authorization is not required

POLICY STATEMENT

Autologous Islet Transplantaton:

BlueCHiP for Medicare and Commercial

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 there is insufficient peer-reviewed scientific literature that demonstrates that the procedure is effective.

Allogeneic Islet Transplantation:

BlueCHiP for Medicare

Allogeneic Pancreatic islet cell transplantation is **covered for BlueCHiP for Medicare members only** with type 1 diabetes who are participating in National Institutes of Health (NIH)-sponsored clinical trials, in accordance with the Centers for Medicare and Medicaid Services (CMS) guidelines. (Effective October 1, 2004) Members with type 1 diabetes must meet the clinical trial recruiting criteria established by the National Institutes of Health (NIH). Information regarding trials which are actively recruiting may be found at www.clinicaltrials.gov.

Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial will continue to be non-covered as there is no FDA approval and therefore, it is considered a contract exclusion.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

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

MEDICAL CRITERIA

None

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. Autologous islet transplantation has been investigated as a technique to prevent this serious morbidity.

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.

Islet cells are subject to regulation 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 under the federal Food, Drug, and Cosmetic Act. Clinical studies to determine safety and effectiveness outcomes of allogeneic islet transplantation must be conducted under FDA investigational new drug (IND) regulation. While at least 35 IND applications have been submitted to the FDA, no center has submitted a biologics license application.

Autologous islet transplantation is proposed in conjunction with pancreatectomy for patients with chronic pancreatitis. 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. Thus, this may be considered medically necessary.

The techniques for allogeneic islet cell transplants are evolving, and the impact on net health outcomes is still uncertain. Moreover, longer follow-up with larger numbers of patients is needed before conclusions can be

drawn about the safety of allogeneic islet transplantation and its impact on diabetes mellitus and associated complications. Thus, allogeneic islet cell transplants are considered not medically necessary as there is no proven efficacy.

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.

COVERAGE

Benefits may 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.

CODING

BlueCHiP for Medicare and Commercial

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

48160

Effective 1/1/12 use the following code for pancreatic islet cell transplantation and laparoscopy:

48999

ICD-9 Diagnosis Code

577.1

ICD-10 Diagnosis Code

K86.1

The following codes are covered for BlueCHiP for Medicare as part of a clinical trial ONLY. Claims should be filed using modifier Q0 (zero)

S2102		
G0341	**G0342**	**G0343**

Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study

RELATED POLICIES

None

PUBLISHED

Provider Update	Nov 2014
Provider Update	Sep 2013
Provider Update	Sep 2012
Provider Update	Sep 2011

Provider Update	Dec 2010
Provider Update	Jul 2009
Provider Update	Jun 2008

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