



**EFFECTIVE DATE:** 06|01|2006  
**POLICY LAST UPDATED:** 02|17|2021

## 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. 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 Transplantation:

#### **Medicare Advantage Plans 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 covered for Medicare Advantage Plans and not medically necessary for Commercial products in all other situations as the evidence is insufficient to determine the effects of the technology on health outcomes.

### Allogeneic Islet Transplantation:

#### **Medicare Advantage Plans**

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

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plan policies. Therefore, Medicare Advantage Plan policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

#### **Commercial Products**

Allogeneic islet transplantation is considered not medically necessary for the treatment of type 1 diabetes as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

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

## BACKGROUND

Performed in conjunction with pancreatectomy, autologous islet transplantation is proposed to reduce the likelihood of insulin-dependent diabetes. Allogeneic islet cell transplantation is also being investigated as a treatment or cure for patients with type 1 diabetes.

## ISLET TRANSPLANTATION

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.

Allogeneic islet transplantation potentially offers an alternative to whole-organ pancreas transplantation. In the case of allogeneic islet cell transplantation, cells are harvested from a 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. However, a limitation of islet transplantation is that two 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. Allogeneic transplantation may be performed in the radiology department. In 2000, a modified immunosuppression regimen increased the success of allogeneic islet transplantation. This regimen is known as the "Edmonton protocol."

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 undergoing total or near-total pancreatectomy who receive autologous pancreas islet transplantation, the evidence includes nonrandomized studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, medication use, resource utilization, and treatment-related morbidity. Autologous islet transplants are performed in the context of total or near-total pancreatectomies to treat intractable pain from chronic pancreatitis. The procedure appears to decrease significantly the incidence of diabetes after total or near-total pancreatectomy in patients with chronic pancreatitis. Also, this islet procedure is not associated with serious complications 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 a randomized controlled trial, registry studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, medication use, resource utilization, and treatment-related morbidity. Results of a 2018 randomized trial have suggested some reduction in the number of severe hypoglycemic incidence annually, but limited follow-up and other trial limitations reduce the certainty in conclusions drawn. A wide range of insulin independence has been reported in case series. There is conflicting evidence on whether allogeneic islet transplantation reduces 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 the effects of the technology on health outcomes.

Medicare covers pancreatic islet transplantation in patients with type 1 diabetes participating in a clinical trial sponsored by the National Institutes of Health. Partial pancreatic tissue transplantation or islet transplantation performed outside a clinical trial are not covered.

## CODING

### Medicare Advantage Plans

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  
ICD-10 Diagnosis Code: **K86.1** Other Chronic Pancreatitis

The HCPCS codes listed below are allowed for Medicare Advantage Plans as part of a CMS approved clinical study. Claims for services rendered as part of a CMS approved clinical study must be billed with an appropriate modifier:

**Modifier Q0** – Investigational clinical service provided in a clinical research study that is in an approved research study (Medicare Advantage Plan claims filed without the Q0 modifier will deny as not covered)

**Modifier Q1** – Routine clinical service provided in a clinical research study that is in an approved clinical research study

**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

**Note:** If you are treating a Medicare Advantage Plan member as part of a CMS approved study, please follow the procedures for correct billing and coding of services found in the policy for Clinical Trials Medicare Advantage Plans.

The following codes are invalid for Medicare Advantage Plans and should be filed with the appropriate “G” code above:

**0584T** Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous

**0585T** Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic

**0586T** Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open

**S2102** Islet cell tissue transplant from pancreas, allogeneic

### 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  
ICD-10 Diagnosis Code: **K86.1** Other Chronic Pancreatitis

The following codes are considered not medically necessary:

**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

**0584T** Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous (effective 1/1/2020)

**0585T** Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic (effective 1/1/2020)

**0586T** Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open (effective 1/1/2020)

**S2102** Islet cell tissue transplant from pancreas, allogeneic

### RELATED POLICIES

Clinical Trials Medicare Advantage Plans

Medicare Advantage Plans National and Local Coverage Determinations

New Technology and Miscellaneous Services

NonReimbursable Health Service Codes

### PUBLISHED

Provider Update, April 2021

Provider Update, March 2020  
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Provider Update, Nov. /Dec. 2018  
Provider Update, November 2017  
Provider Update, January 2017  
Provider Update, November 2014  
Provider Update, April 2015

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