

Pancreatic Islet Cell Transplantation

Last Review Date: November 12, 2021

Number: MG.MM.TR.02C6

Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Background

Chronic pancreatitis is a complex disease that originates from a variety of causes. Progressive inflammation of acinar tissue may affect endocrine tissue function, thereby progressively damaging the islets of Langerhans, resulting in diabetes. The course of the disease is often punctuated by repeated pancreatic duct stenting and/or partial pancreatectomy. Some patients undergo total pancreatectomy for pain relief, which leads to immediate and total insulin deficiency diabetes.

Autologous islet transplantation is a technique performed as an adjunct to a total or near total pancreatectomy in order to salvage and transplant beta cells to prevent complications of chronic diabetes. During the pancreatectomy, a suspension is created by mixing plasma and the isolated islet cells collected from the individual's own resected pancreatic specimen. This suspension is then injected into the portal vein of the liver where the cells function as a free graft.

Allogeneic pancreatic islet cell transplantation utilizes human donor cells (other than those of the recipient); **xenotransplantation** utilizes porcine cells, both are alternative procedures that require lifelong immunosuppression to prevent graft-rejection and recurrence of the autoimmune process. (See [Limitations/Exclusions](#))

Guideline

Note: This guideline is specific to pancreatic islet cell transplantation for members with chronic pancreatitis who require pancreatectomy. For whole organ (pancreas) transplant to treat Type 1 diabetes, members and providers are directed to call the EmblemHealth Transplant Program for case management services at 1-800-447-0768.

Members with chronic pancreatitis are eligible for autologous pancreatic islet cell transplantation when the following criteria are met; both:

1. Severe pain refractory to medical management.
2. Transplantation is adjunctive to total/near-total pancreatectomy.

Limitations/Exclusions

The following types of transplantation are not considered medically necessary for the treatment of Type 1 diabetes due to insufficient evidence of therapeutic value:

1. Allogeneic islet cell transplantation.
2. Islet cell xenotransplantation.

Applicable Procedure Codes

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
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation

Applicable ICD-10 Diagnosis Codes

K86.0	Alcohol-induced chronic pancreatitis
K86.1	Other chronic pancreatitis
Z90.410	Acquired total absence of pancreas
Z90.411	Acquired partial absence of pancreas

References

- Aguayo-Mazzucato C, Bonner-Weir S. Stem cell therapy for type 1 diabetes mellitus. *Nat Rev Endocrinol*. 2010;6(3):139-48.
- Alejandro R, Barton FB, Hering BJ, et al. 2008 Update from the Collaborative Islet Transplant Registry. *Transplantation*. 2008; 86(12):1783-8.
- American Diabetes Association. Position Statement. Pancreas Transplantation in Type 1 Diabetes. 2004. http://care.diabetesjournals.org/content/27/suppl_1/s105. Accessed November 18, 2021.
- American Diabetes Association. Position Statement. Pancreas and Islet Transplantation in Type 1 Diabetes. 2006. <http://care.diabetesjournals.org/content/29/4/935.short>. Accessed November 18, 2021.
- Badet L, Benhamou PY, Wojtusciszyn A, et al; GRAGIL Group. Expectations and strategies regarding islet transplantation: metabolic data from the GRAGIL 2 trial. *Transplantation*. 2007;84(1):89-96.
- Barton FB, Rickels MR, Alejandro R, et al. Improvement in outcomes of clinical islet transplantation: 1999-2010. *Diabetes Care*. 2012; 35(7):1436-45.
- Bramis K, Gordon-Weeks AN, Friend PJ, et al. Systematic review of total pancreatectomy and islet autotransplantation for chronic pancreatitis. *Br J Surg*. 2012;99(6):761-6.
- Centers for Medicare & Medicaid Services. National Coverage Determination for Islet Cell Transplantation in the Context of a Clinical Trial. October 2004. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=286&ncdver=1&DocID=260.3.1&kq=true&SearchType=Advanced&bc=IAAAAAgAAAAAA%3d%3d&>. Accessed November 18, 2021.
- Chinnakotla S, Radosevich DM, Dunn TB, et al. Long-term outcomes of total pancreatectomy and islet auto transplantation for hereditary/genetic pancreatitis. *J Am Coll Surg*. 2014; 218(4):530-43.
- Dong M, Parsaik AK, Erwin PJ, et al. Systematic review and meta-analysis: islet autotransplantation after pancreatectomy for minimizing diabetes. *Clin Endocrinol (Oxf)*. 2011;75(6):771-9.

Fiorina P, Secchi A. Pancreatic islet cell transplant for treatment of diabetes. *Endocrinol Metab Clin North Am.* 2007; 36(4):999-1013.

Frank A, Deng S, Huang X, et al. Transplantation for type I diabetes: comparison of vascularized whole-organ pancreas with isolated pancreatic islets. *Ann Surg.* 2004;240(4):631-643.

Froud T, Ricordi C, Baidal DA, et al. Islet transplantation in type 1 diabetes mellitus using cultured islets and steroid-free immunosuppression: Miami experience. *Am J Transplant.* 2005;5(8):2037-2046.

Hering BJ, Wijkstrom M, Graham ML, et al. Prolonged diabetes reversal after intraportal xenotransplantation of wild-type porcine islets in immunosuppressed nonhuman primates. *Nat Med* 2006; 12:301.

National Institute of Diabetes and Digestive and Kidney Diseases. Pancreatic Islet Transplantation. <https://www.niddk.nih.gov/health-information/diabetes/overview/insulin-medicines-treatments/pancreatic-islet-transplantation>. Accessed November 18, 2021.

National Institute for Health and Clinical Excellence. Allogenic pancreatic islet cell transplantation for type 1 diabetes mellitus. 2008. <http://www.nice.org.uk/Guidance/IPG257>. Accessed November 18, 2021.

National Institute for Health and Clinical Excellence. Autologous pancreatic islet cell transplantation for improved glycemic control after pancreatectomy. 2008. <http://www.nice.org.uk/Guidance/IPG274>. Accessed November 18, 2021.

O'Connell PJ, Holmes-Walker DJ, Goodman D, et al. Multicenter Australian trial of islet transplantation: improving accessibility and outcomes. *Am J Transplant.* 2013;13(7):1850-8.

Pavlakakis M, Khwaja K. Pancreas and islet cell transplantation in diabetes. *Curr Opin Endocrinol Diabetes Obes.* 2007;14(2):146-150.

Piper M, Seidenfeld J, Aronson N. Islet transplantation in patients with type 1 diabetes mellitus. *Evid Rep Technol Assess (Summ).* 2004;(98):1-6.

Posselt AM, Szot GL, Frassetto LA, et al. Islet transplantation in type 1 diabetic patients using calcineurin inhibitor-free immunosuppressive protocols based on T-cell adhesion or costimulation blockade. *Transplantation.* 2010;90(12):1595-601.

Ramesh A, Chhabra P, Brayman KL. Pancreatic islet transplantation in type 1 diabetes mellitus: an update on recent developments. *Curr Diabetes Rev.* 2013;9(4):294-311.

Rickels MR, Kong SM, Fuller C, et al. Improvement in insulin sensitivity after human islet transplantation for type 1 diabetes. *J Clin Endocrinol Metab.* 2013;98(11):E1780-5.

Robertson RP, Lanz KJ, Sutherland DE, Kendall DM. Prevention of diabetes for up to 13 years by autoislet transplantation after pancreatectomy for chronic pancreatitis. *Diabetes.* 2001;50(1):47-50.

Shapiro AM, Ricordi C, Hering BJ, et al. International trial of the Edmonton protocol for islet transplantation. *N Engl J Med.* 2006;355(13):1318-1330.

Sutherland DE, Radosevich DM, Bellin MD, et al. Total pancreatectomy and islet autotransplantation for chronic pancreatitis. *J Am Coll Surg.* 2012;214(4):409-24.

Thompson DM, Meloche M, Ao Z, et al. Reduced progression of diabetic microvascular complications with islet cell transplantation compared with intensive medical therapy. *Transplantation.* 2011;91(3):373-8.

FDA U.S. Food & Drug Administration. Guidance for industry: Considerations for Allogeneic Pancreatic Islet Cell Products. September 2009. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-allogeneic-pancreatic-islet-cell-products>. Accessed November 18, 2021.

Vantghem MC, Raverdy V, Balavoine AS, et al. Continuous glucose monitoring after islet transplantation in type 1 diabetes: an excellent graft function (beta-score greater than 7) is required to abrogate hyperglycemia, whereas a minimal function is necessary to suppress severe hypoglycemia (beta-score greater than 3). *J Clin Endocrinol Metab.* 2012; 97(11):E2078-83.

Wahoff DC, Papalois BE, Najarian JS, et al. Autologous islet transplantation to prevent diabetes after pancreatic resection. *Ann Surg.* 1995;222(4):562-579.

Webb MA, Illouz SC, Pollard CA, et al. Islet auto transplantation following total pancreatectomy: a long-term assessment of graft function. *Pancreas.* 2008; 37(3):282-7.