

# MedStar Health, Inc.

## POLICY AND PROCEDURE MANUAL

Policy Number: PA.095.MH  
Last Review Date: 11/14/2019  
Effective Date: 01/01/2020

### PA.095.MH – Pancreatectomy with Autologous Islet Cell Transplantation

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Pancreatectomy with Autologous Islet Cell Transplantation** medically necessary for the following indications:

1. Chronic pancreatitis with intractable pain; or
2. Acute relapsing pancreatitis (ARP) with episodes that are frequent, disruptive and persist over time; or
3. Intractable pain from other confirmed benign disease of the pancreas including pancreatic pseudocysts, cystic neoplasms (e.g. intrapapillary mucinous neoplasms IPMN), insulinomas, or neuroendocrine and other tumors.  
**And**
4. Other treatments have failed to adequately control symptoms including:
  - a. Conservative medical therapy including pain management and dietary modifications and/or
  - b. Endoscopic drainage and/or stenting of pancreatic ducts (or the member is not a candidate for this treatment) and/or
5. Intractable pain from other confirmed benign disease of the pancreas including pseudocysts, cystic neoplasms, insulinomas, or neuroendocrine tumors.  
**And**
6. The member is in need of a total pancreatectomy, or partial pancreatectomy with possibility of future complete pancreatectomy  
**And**
7. The member is non-diabetic at the time of pancreatectomy or is diabetic, but the C-peptide level demonstrates evidence of beta cell function as stable

Note: If the member does not require insulin pre- pancreatectomy, C-peptide levels are not needed to confirm there is beta cell function

#### Limitations

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Islet Cell extraction for Auto-transplantation can be performed only in facilities that are Food and Drug Administration (FDA) approved for extraction of Islet cells from the Pancreas.

Experimental and Investigational and therefore not covered for chronic pancreatitis:

- Allogeneic Islet Cell Transplant
- Xenogeneic Islet Cell Transplant (all xenogeneic transplants are considered experimental and investigational)
- All other indications not listed in this policy.

## Background

Chronic pancreatitis is the inflammation of the pancreas that worsens with time ultimately leading to the destruction of the gland. It can lead to exocrine pancreatic insufficiency and diabetes. Treatment options include pain management and dietary modifications initially, but chronic and recurrent episodes may lead to a autologous islet cell transplantation.

A typical islet cell transplant requires over 500,000 islet cells, but varies depending on the recipient's weight. One of the desired patient outcomes is insulin independence. Elimination of clinically significant hypoglycemia episodes and improved glucose control are other important patient outcomes. One or more pancreata are obtained from donor(s). The islets must be removed within hours after the recovery of the donor pancreas to ensure viability. The islet cells are transplanted by injection into the portal vein of the recipient either using direct visualization, guided ultrasound or percutaneously. The islet cell transplant may be performed alone, in combination with a kidney transplant, or after a kidney transplant. Islet recipients require immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care is necessary for each trial participant.

One of the goals of pancreatectomy with autologous islet cell transplantation is to prevent the onset of diabetes, reduce the severity of the disease, reduce the pain and ultimately improve one's quality of life.

## Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
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Code	Description
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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

### References

1. Bellin MD, Carlson AM, Kobayashi T, et al. Outcome after pancreatectomy and islet autotransplantation in a pediatric population. *J Pediatr Gastroenterol Nutr.* 2008;47:37-44. <http://www.ncbi.nlm.nih.gov/pubmed/18607267>
2. Bellin MD, Freeman ML, Schwarzenberg SJ, et al. Quality of life improves for pediatric patients after total pancreatectomy and islet autotransplant for chronic pancreatitis. *Clin Gastroenterol Hepatol.* 2011 Sep;9(9):793-799. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3163759/pdf/nihms311960.pdf>
3. Bottino R, Bertera S, Grupillo M, et al. Isolation of human islets for autologous islet cell transplantation in children and adolescents with chronic pancreatitis. *J Transplant.* 2012;2012:642787. doi: 10.1155/2012/642787 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3306977/>
4. Gaba RC, Garcia-Roca R, Oberholzer J. Pancreatic islet cell transplantation: An update for interventional radiologists. *J Vasc Interv Radiol.* 2012;23:583-594. <https://www.ncbi.nlm.nih.gov/pubmed/22417970>
5. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD). No. 260.3.1 - Islet Cell Transplantation in the Context of a Clinical Trial, Effective Date: 10/1/2004 [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=286&ncdver=1&DocID=260.3.1&list\\_type=ncd&bc=gAAAAAgAAAA&](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=286&ncdver=1&DocID=260.3.1&list_type=ncd&bc=gAAAAAgAAAA&)
6. Centers for Medicare and Medicaid Services (CMS). CMS Manual, Claims Processing. Pub 100-04, Transmittal 261, Change Request 3385, Date: 07-30-2004 Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health Clinical Trial. <http://www.cms.hhs.gov/transmittals/downloads/R261CP.pdf>

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7. Centers for Medicare and Medicaid Services (CMS). CMS Manual System. Pub 100-04, Transmittal 986, Change Request 5140. Date: June 16, 2006: Subject: Payment for Islet Cell Transplantation in NIH-Sponsored Clinical Trials. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R986CP.pdf>
8. Dunderdale J, McAuliffe JC, McNeal SF, et al. Should pancreatectomy with islet cell autotransplantation in patients with chronic alcoholic pancreatitis be abandoned? *J Am Coll Surg*. 2013 Apr; 216(4):591-596; discussion 596-598. doi: 10.1016/j.jamcollsurg.2012.12.043. <http://www.ncbi.nlm.nih.gov/pubmed/23521936>
9. Issa Y, Bruno MJ, Bakker OJ, et al. Treatment options for chronic pancreatitis. *Nature Reviews Gastroenterology & Hepatology* 11, 556-564 (2014). <http://www.nature.com/nrgastro/journal/v11/n9/full/nrgastro.2014.74.html?message-global=remove>
10. Ong SL, Gravante G, Pollard CA, et al. Total pancreatectomy with islet autotransplantation: an overview. *HPB (Oxford) [J International Hepato-Pancreato-Biliary Assn]*. 2009; 11 (8):613-621. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799613/pdf/hpb0011-0613.pdf>
11. Rodriguez Rilo HL, Ahmad SA, D'Alessio D, et al. Total pancreatectomy and autologous islet cell transplantation as a means to treat severe chronic pancreatitis." *J Gastrointest Surg*. 2003; 7(8):978-989. <http://www.ncbi.nlm.nih.gov/pubmed/14675707>
12. Sutherland DE, Gruessner AC, Carlson AM, et al., Islet autotransplant outcomes after total pancreatectomy: a contrast to islet allograft outcomes. *Transplantation*. 2008; 86:1799-1802. <http://www.ncbi.nlm.nih.gov/pubmed/19104425>
13. Sutherland DE, et al. Total Pancreatectomy and Islet Autotransplantation for Chronic Pancreatitis. *J Am Coll Surg*. 2012; 214:409-24. <https://www.ncbi.nlm.nih.gov/pubmed/22397977>
14. The University of Chicago Medical Center: Autologous Islet Cell Transplantation, © 2015. Accessed: October 28, 2019. Available at: <http://www.uchospitals.edu/specialties/pancreas/pancreatitis/ait.html>
15. U.S. Preventive Services Task Force: Recommendations for adults. Current as of March 2015. Accessed: 10/28/2019. <http://www.uspreventiveservicestaskforce.org/Page/Name/recommendations>

### Disclaimer:

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