

Policy Number: PA.095.MPC Last Review Date: 08/15/2024 Effective Date: 09/01/2024

PA.095.MPC Pancreatectomy with Autologous Islet Cell Transplantation

Maryland Physicians Care 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 cystic fibrosis, 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:
 - 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)

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- 5. The member is in need of a total pancreatectomy, or partial pancreatectomy with possibility of future complete pancreatectomy.
- 6. 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.

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

Limitations

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.



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Contraindications

Total Pancreatectomy w Autologous Islet Cell Transplant (TPAIT) is contraindicated in patients with C-peptide negative diabetes, type 1 diabetes, portal vein thrombosis, portal hypertension, advanced liver disease or cardiopulmonary disease, and pancreatic cancer. Psychosocial contraindications for TPAIT such as active alcohol abuse, active illicit substance use, and untreated/uncontrolled psychiatric disease that could impair the patient's ability to adhere to complicated medical management.

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.

Autologous islet cell transplantation is an alternative for persons undergoing total pancreatectomy for severe, refractory chronic pancreatitis. Near total or total pancreatic resection can alleviate pain in patients with severe pancreatitis. Autologous islet cell transplantation can preserve islet cell function in patients undergoing this procedure. 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.

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	
Code	Description
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



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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
- 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/
- 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
- 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
- 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/Transmittals/downloads/R986CP.pdf
- 8. Dunderdale J, McAuliffe JC, McNeal SF, et al. Should pancreatectomy with islet cell auto transplantation in patients with chronic alcoholic pancreatitis be abandoned? J Am Coll Surg. 2013 Apr; 216(4):591-596; discussion 596-598. doi:



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- 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 Medicine: Pancreas and Islet Transplant.

 https://www.uchicagomedicine.org/conditions-services/transplant/pancreas-islet-transplant
- 15. U.S. Preventive Services Task Force: Recommendations for adults. http://www.uspreventiveservicestaskforce.org/Page/Name/recommendations
- 16. Abu-El-Haija M, Anazawa T, Beilman GJ, et al. The role of total pancreatectomy with islet autotransplantation in the treatment of chronic pancreatitis: A report from the International Consensus Guidelines in chronic pancreatitis. Pancreatology. 2020 Apr 14.
- https://pubmed.ncbi.nlm.nih.gov/32327370/

 17. Bellin M.D., Freeman M.L., Gelrud A., Slivka A., Clavel A., Humar A., Schwarzenberg S.J., Lowe M.E., Rickels M., Whitcomb D.C., et al. Total pancreatectomy and islet autotransplantation in chronic pancreatitis: Recommendations from PancreasFest.

 Pancreatology 2014:14:27–35. doi: 10.1016/j.pan.2013.10.009
 - *Pancreatology.* 2014;14:27–35. doi: 10.1016/j.pan.2013.10.009. https://pubmed.ncbi.nlm.nih.gov/24555976/
- 18. Abu-El-Haija, Maisam, et. al. The role of total pancreatectomy with islet autotransplantation in the treatment of chronic pancreatitis: A report from the



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International Consensus Guidelines in chronic pancreatitis. Pancreatology, volume 20, Issue 4, 2020, pp. 762-771, ISSN 1424-3903. https://www.sciencedirect.com/science/article/abs/pii/S1424390320301344

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