

Pancreas and Islet Cell Transplants

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Effective Date 7/1992

Next Review Date 3/15/2024

Coverage Policy Surgical 27

<u>Version</u> 4

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details $\underline{*}$.

Purpose:

This policy addresses the medical necessity of surgery for Pancreas and Islet Cell Transplants.

Description & Definitions:

Islet cell transplant is a surgical procedure where healthy isolated islets from a healthy pancreas are transplanted into a diseased pancreas.

Pancreas transplant alone (PTA) is a surgical procedure where a healthy pancreas replaces a diseased pancreas.

Pancreas-after-kidney transplant (PAK) is a surgical procedure where a healthy pancreas replaces a diseased pancreas after a previous kidney transplant.

Simultaneous pancreas-kidney transplant (SPKT) is a surgical procedure where a healthy pancreas and kidneys replace a diseased pancreas and kidneys.

Total pancreatectomy with islet autotransplant [TPIAT] is a surgical procedure to completely remove the pancreas and transplant the patient's own islet cells back through the portal vein.

Criteria:

Pancreas transplants are considered medically necessary for 1 or more of the following:

- Autologous pancreatic islet cell transplantation for individuals for 1 or more of the following:
 - As an adjunct to a total pancreatectomy for individuals with chronic pancreatitis
 - o As an adjunct to a near total pancreatectomy for individuals with chronic pancreatitis
- Pancreas transplants alone (PTA) for individuals with All of the following:
 - Satisfactory kidney function (creatinine clearance greater than 40 mL/min)
 - Adequate cardiac status
 - o Absence of ongoing infections that are not effectively treated
 - Absence of uncontrolled human immunodeficiency virus/acquired immunodeficiency syndrome infection (HIV/AIDS) with AII of the following:

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- Cluster of differentiation 4 (CD4) counts greater than 200 cells/mm3 for more than 6 months
- Human immunodeficiency virus ribonucleic acid (HIV-1 RNA [viral load]) is undetectable
- On stable antiviral therapy for more than 3 months
- No other complications from acquired immunodeficiency syndrome (AIDS)
- o Individual with 1 or more of the following:
 - No malignancy (except for of non-melanomatous skin cancer)
 - Malignancy has been completely resected
 - Malignancy has been adequately treated such that the risk of recurrence is small
- Documentation of compliance with medical management
- Pancreas after kidney transplants (PAK) for individuals with All of the following:
 - Adequate cardiac status indicated by All of the following:
 - No angiographic evidence of significant coronary artery disease
 - Ejection fraction (EF) greater than or equal to 40%
 - No myocardial infarction in the last 6 months
 - Negative stress test
 - Individual with absence of ongoing infection that are not effectively treated
 - o Individual with absence of uncontrolled human immunodeficiency virus/acquired immunodeficiency syndrome infection with **All** of the following:
 - Custer of differentiation 4 (CD4) counts greater than 200 cells/mm3 for more than 6 months
 - Human immunodeficiency virus ribonucleic acid (HIV-1 RNA [viral load]) is undetectable
 - On stable antiviral therapy for more than 3 months
 - No other complications from acquired immunodeficiency syndrome (AIDS)
 - Individual with 1 or more of the following:
 - No malignancy (except for of non-melanomatous skin cancer)
 - Malignancy has been completely resected
 - Malignancy has been adequately treated such that the risk of recurrence is small
 - o Individual with documentation of compliance with medical management
- Simultaneous kidney-pancreas transplants (SPKT) for individuals with All of the following:
 - Adequate cardiac status indicated by All of the following:
 - No angiographic evidence of significant coronary artery disease
 - Ejection fraction (EF) greater than or equal to 40%
 - No myocardial infarction in the last 6 months
 - Negative stress test
 - o Absence of ongoing infection that are not effectively treated
 - Absence of uncontrolled human immunodeficiency virus/acquired immunodeficiency syndrome infection with **All** of the following:
 - Custer of differentiation 4 (CD4) counts greater than 200 cells/mm3 for more than 6 months
 - Human immunodeficiency virus ribonucleic acid (HIV-1 RNA [viral load]) is undetectable
 - On stable antiviral therapy for more than 3 months
 - No other complications from acquired immunodeficiency syndrome (AIDS)
 - o Individual with 1 or more of the following:
 - No malignancy (except for of non-melanomatous skin cancer)
 - Malignancy has been completely resected
 - Malignancy has been adequately treated such that the risk of recurrence is small
 - o Individual with documentation of compliance with medical management

Pancreas transplants are considered **not medically necessary** any use other than those indicated in clinical criteria, to include but not limited to:

• allogeneic (cadaver) pancreatic islet cell transplantation and pancreatic islet xenotransplantation

Coding:

Medically necessary with criteria:

Coding	Description
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
48554	Transplantation of pancreatic allograft

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Considered Not Medically Necessary:

Coding	Description
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

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2022: March
- 2020: January, April
- 2013: January
- 2012: January
- 2011: May
- 2010: January
- 2009: January
- 2008: January
- 2005: December
- 2003: April
- 2002: March
- 1999: March
- 1996: October

Reviewed Dates:

- 2023: March
- 2021: March
- 2018: December
- 2017: November
- 2016: January
- 2015: January
- 2014: January
- 2007: December
- 2006: June
- 2005: September, November
- 2004: April, September
- 2003: March
- 2001: November
- 2000: October
- 1998: December
- 1995: October

Effective Date:

July 1992

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References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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(2023). Retrieved Jan 17, 2023, from AIM Specialty Health:

https://guidelines.aimspecialtyhealth.com/?s=Pancreas+transplant&et_pb_searchform_submit=et_search_proccess&et_pb_search_cat=11%2C1%2C96&et_pb_include_posts=yes

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Pancreas Transplants. (2012, March). Retrieved Jan 17, 2023, from American Society of Transplantation: https://www.myast.org/sites/default/files/pdfs/getting_new_pancreas.pdf

Pancreatic Adenocarcinoma. (2022, Feb). Retrieved Jan 17, 2023, from National Comprehensive Cancer Network (NCCN): https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf

Pancreatic Islet Cell Transplantation. (2022, Jun 15). Retrieved Jan 17, 2023, from Cigna 2: https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0107_coveragepositioncriteria_pancreatic_islet_transplantation.pdf

SS ACT - Attachment 3.1- A&B (07/02/2021). (2021). Retrieved Jan 17, 2023, from STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT State of VIRGINIA: https://www.dmas.virginia.gov/media/3355/31a-b-s1-amount-duration-and-scope-categorically-and-medically-needy.pdf

Update on Pancreatic Transplantation in the Management of Diabetes. (2021, Aug 17). Retrieved Jan 17, 2023, from Endotext - Endocrinology Book: https://www.ncbi.nlm.nih.gov/books/NBK278979/

Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

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Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

Pancreas transplant, PTA, simultaneous kidney-pancreas transplant, SPKT, pancreas after kidney transplant, PAK, islet cell transplant, kidney transplant, Pancreatectomy, insulin-independent, euglycemic state, diabetic, end stage renal disease, ESRD, Surgical 27

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