

## Pancreas and Islet Cell Transplants

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**All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.\*.**

### Purpose:

This policy addresses 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 of the following**:

- **Autologous pancreatic islet cell transplantation** for individuals for **1 of the** following:
  - As an adjunct to a total pancreatectomy for individuals with chronic pancreatitis
  - 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

- Absence of ongoing infections that are not effectively treated
- Absence of uncontrolled human immunodeficiency virus/acquired immunodeficiency syndrome infection (HIV/AIDS) with **All of the** following:
  - Cluster of differentiation 4 (CD4) counts greater than 200 cells/mm<sup>3</sup> 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 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
  - Individual with absence of uncontrolled human immunodeficiency virus/acquired immunodeficiency syndrome infection with **All of the** following:
    - Cluster of differentiation 4 (CD4) counts greater than 200 cells/mm<sup>3</sup> 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 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
  - 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
  - Absence of ongoing infection that are not effectively treated
  - Absence of uncontrolled human immunodeficiency virus/acquired immunodeficiency syndrome infection with **All of the** following:
    - Cluster of differentiation 4 (CD4) counts greater than 200 cells/mm<sup>3</sup> 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 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
  - 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

#### 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

## 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\\_procce&et\\_pb\\_search\\_cat=11%2C1%2C96&et\\_pb\\_include\\_posts=yes](https://guidelines.aimspecialtyhealth.com/?s=Pancreas+transplant&et_pb_searchform_submit=et_search_procce&et_pb_search_cat=11%2C1%2C96&et_pb_include_posts=yes)

National Coverage Determination (NCD) for Pancreas TRANSPLANTS (260.3). (2006). Retrieved Jan 17, 2023, from Centers for Medicare & Medicaid Services NCD: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=107&ncdver=3&keyword=Pancreas%20TRANSPLANT&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>

Pancreas and islet transplantation in diabetes mellitus. (2022, Aug 26). Retrieved Jan 17, 2023, from UpToDate: [https://www.uptodate.com/contents/pancreas-and-islet-transplantation-in-diabetes-mellitus?search=Pancreas%20transplant&source=search\\_result&selectedTitle=1~74&usage\\_type=default&display\\_rank=1](https://www.uptodate.com/contents/pancreas-and-islet-transplantation-in-diabetes-mellitus?search=Pancreas%20transplant&source=search_result&selectedTitle=1~74&usage_type=default&display_rank=1)

Pancreas transplant. (2023). Retrieved Jan 16, 2023, from HAYES: <https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Pancreas%2520transplant%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522source>

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](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](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](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: \*

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded

by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to “correct or ameliorate” (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

### 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