

Pancreas and Islet Cell Transplants, Surgical

27

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Coverage Policy	Surgical 27
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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 and Islet Cell Transplants are considered medically necessary for **one or more of the following**:

- **Autologous pancreatic islet cell transplantation** is considered medically necessary as an adjunct to a near or total pancreatectomy for individuals with chronic pancreatitis.

- **Pancreas transplants alone (PTA)** is considered medically necessary for FAMIS children and Cardinal members under 21 years when **ALL** the following criteria are met:
 - The individual has type 1 or type 2 diabetes mellitus and **ALL** of the following:
 - Labile diabetes mellitus with documented life-threatening hypoglycemic unawareness and/or frequent hypoglycemic episodes despite optimal medical management
 - Insulin requiring diabetes for > 5 years receiving ≤ 1 unit/kg/day
 - BMI < 30
 - Age < 60
 - No history of major vascular events such as bilateral limb amputations and disabling CVA
 - Not actively smoking.
 - Satisfactory kidney function (creatinine clearance greater than 40 mL/min)
 - The individual had a social and psychological evaluation and any identified issues have been addressed.
 - The individual has been evaluated and the procedure has been approved by the institutional transplant committee.
 - The individual does not have **one or more** of the following diagnoses:
 - Non-correctable coronary artery disease or ejection fraction (LVEF, EF) < 40%
 - Systemic or uncontrolled infection including sepsis.
 - Significant uncorrectable life-limiting medical conditions
 - Severe end-stage organ damage that would have an impact on patient survival (pre-procedural clearance must be obtained from the appropriate specialist)
 - Active untreated or untreatable malignancy (Please see American Society of Transplantation guidelines (Al-Adra et al. (2021) recommendations for suitability and timing of a solid organ transplant following successful treatment of malignancy).
 - Irreversible, severe brain damage
 - Active substance use disorders.
 - Uncontrolled infection with human immunodeficiency virus (HIV) (Patients with human immunodeficiency virus (HIV) infection must be on a highly active antiretroviral therapy (HAART) regimen and there must be documented evidence of sustained viral load suppression.)
 - None of the above

- **Simultaneous kidney-pancreas transplants (SPKT) or Pancreas after Kidney Transplant (PAK)** is considered medically necessary for FAMIS children and Cardinal members under 21 years when **ALL of the** following criteria are met:
 - The individual qualifies for kidney transplant.
 - The individual has type 1 or 2 diabetes mellitus.
 - The individual had a social and psychological evaluation and any identified issues have been addressed.
 - The individual has been evaluated and the procedure has been approved by the institutional transplant committee.
 - The individual does **NOT** have **one or more** of the following diagnoses:
 - Non-correctable coronary artery disease or ejection fraction (LVEF, EF) < 40%
 - Systemic or uncontrolled infection including sepsis.
 - Significant uncorrectable life-limiting medical conditions
 - Severe end-stage organ damage that would have an impact on patient survival (pre-procedural clearance must be obtained from the appropriate specialist)
 - Active untreated or untreatable malignancy (Please see American Society of Transplantation Guidelines (Al-Adra et al. (2021) recommendations for suitability and timing of a solid organ transplant following successful treatment of malignancy).
 - Irreversible, severe brain damage
 - Active substance use disorders.
 - Uncontrolled infection with human immunodeficiency virus (HIV) (Patients with human immunodeficiency virus (HIV) infection must be on a highly active antiretroviral therapy (HAART) regimen and there must be documented evidence of sustained viral load suppression.)
 - None of the above.

Pancreatic islet xenotransplantation is considered not medically necessary as it has not been shown to improve outcomes in comparison to other approved treatments.

For medical necessity criteria for Lantidra please see Sentara Health Plan pharmacy prior authorization information.

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:

- 2024: July – criteria updated references updated
- 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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https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

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National Coverage Determination (NCD) Pancreas Transplants 260.3. (2006). Retrieved Feb 2024, from CMS: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=107&ncdver=3&bc=0>

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