

Pancreas and Islet Cell Transplants, Surgical

27

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[Coverage Policy](#) Surgical 27
[Version](#) 8

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details [*](#).

Purpose:

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

Description & Definitions:

This policy addresses surgery for pancreas and autologous islet cell transplants. Medical necessity guidelines for Lantidra may be found through the Sentara Health Plan pharmacy prior authorization information.

Islet cell transplant is a surgical procedure where healthy isolated islets from a healthy pancreas are transplanted into a diseased pancreas. Lantidra is a commercially available suspension of purified cadaveric pancreatic cells.

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 kidney 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 (41860)** 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 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 individuals 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: August
- 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:

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

(2024). Retrieved Feb 2024, from MCG 27th Edition: <https://careweb.careguidelines.com/ed27/index.html>

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Pancreatic Adenocarcinoma. (December 13, 2023). Retrieved Feb 2024, from National Comprehensive Cancer Network (NCCN): https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf

Provider Manual Title: Practitioner. (Revision Date: 12/2/2022). Retrieved Feb 2024, from DMAS - Commonwealth of Virginia: https://vamedicaid.dmas.virginia.gov/sites/default/files/2023-08/Physician-Practitioner%20Manual%20App%20D%20%28Updated%2012.2.22%29_Final.pdf

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: *

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.

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