

Solid Organ Transplantations, Surgical 236

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Coverage Policy Surgical 236
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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.*.

Description & Definitions:

Heart-Lung Transplantation is a procedure to replace the heart and lungs with a donated heart and lungs in a single operation. **Intestinal and Visceral/multivisceral transplantation** is a surgical procedure with cadaver or living donor organ to replace and repair the damaged structure to restore proper function.

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

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

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

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

- Allogeneic islet cell transplantation
- Autologous islet cell transplantation
- Xenologous (also known as Heterologous)

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.

Other common names: cardiopulmonary transplantation, small bowel transplant, isolated small bowel, combined small bowel/liver, and multivisceral transplant, (ITx), Pancreas Transplantation (PTx)

Criteria:

Solid Organ Transplantation is considered medically necessary for **1 or more** of the following:

- **Heart-Lung Transplant** are considered medically necessary if the individual with end-stage pulmonary vascular disease with end-stage non-reversible cardiac disease secondary to **1 or more** of the following:
 - Eisenmenger syndrome with a cardiac defect not correctable by surgical repair
 - Individual is appropriate for single or double lung transplantation and who have severe cardiac disease not otherwise treatable
 - Primary pulmonary hypertension
- **Intestinal Transplant With or Without Combined Liver Transplant or Other Visceral Organs** are considered medically necessary for **1 or more** of the following:
 - **Intestinal Transplant without Combined Liver Transplant** is considered medically necessary if the individual presents with **1 or more** of the following:
 - Irreversible intestinal failure with associated life-threatening complications
 - Secretory diarrhea of childhood may have high mortality/morbidity due to their underlying disease and therefore can be considered for intestine transplant evaluation in the absence of life-threatening complications with **ALL** of the following:
 - Isolated intestinal transplants are performed in the presence of cholestasis only when the liver disease is felt to be reversible.
 - Inability to maintain fluid and electrolyte balance
 - Recurrent sepsis as a result of either line sepsis or intestinal stasis
 - Dependent on TPN with loss of or impending loss of (using last major vessel) vascular access
 - Non-reconstructible gastrointestinal (GI) tract
 - **Intestinal Transplant with Combined Liver Transplant or other visceral Organs/ multivisceral organs** (Liver/small bowel/pancreas with or without addition of stomach or colon) are considered medically necessary for FAMIS children and Cardinal members under 21 years when ALL of the following criteria are met:
 - Assessment of Individual required **1 or more** of the following:
 - Biopsy proven fibrotic changes within the liver indicating that the TPN associated liver dysfunction is irreversible
 - Clinical assessment of significant portal hypertension (such as hypersplenism) where biopsy may not be available or warranted or considered safe to perform
 - Individual presents with diagnosis and symptoms of **1 or more** of the following:
 - Irreversible intestinal failure with associated life-threatening complications
 - Secretory diarrhea of childhood may have high mortality/morbidity due to their underlying disease and therefore can be considered for intestine transplant evaluation in the absence of life-threatening complications with **ALL** of the following:
 - Dependent on TPN with cholestatic liver disease as defined by elevated direct bilirubin. If cholestasis is advanced, or cirrhosis is present, a combined liver/intestine transplant may be considered
 - Inability to maintain fluid and electrolyte balance
 - Recurrent sepsis as a result of either line sepsis or intestinal stasis
 - Dependent on TPN with loss of or impending loss of (using last major vessel) vascular access
 - Non-reconstructible gastrointestinal (GI) tract
 - Transplantation with Multivisceral organs (Liver/small bowel/pancreas with or without addition of stomach or colon) for **1 or more** of the following:
 - Desmoid tumors
 - Severe gastric or antroduodenal motility disorder (pseudo-obstruction)
 - Technical considerations that make the anastomoses of one or more of the separate organs problematic when compared to an en bloc dissection and transplantation that requires fewer vascular and intestinal anastomoses
 - Individual listed for multivisceral transplantation without TPN dependency require special case review
 - **Retransplantation of Intestinal Transplant With or Without Combined Liver Transplant or Other Visceral Organs** may occur when there is a failed prior intestinal transplantation, including non-function of the grafted organ, acute rejection requiring enterectomy or chronic rejection

- **Pancreas and Islet Cell Transplants** are considered medically necessary for **1 or more** of the following:
 - **Autologous islet cell transplantation** is considered medically necessary as an adjunct to a near or total pancreatectomy for individuals with 1 or more of the following:
 - chronic pancreatitis
 - Non-malignant conditions is an accepted treatment to prevent the immediate onset of insulin-dependent diabetes mellitus.
 - **Pancreas transplants alone (PTA)** Pancreas transplants alone (PTA) is considered medically necessary for FAMIS children and Cardinal members under 21 years when **ALL** of the following criteria are met:
 - Individual has **Type 1 or type 2** diabetes mellitus with **1 or more** of the following:
 - Type 1 diabetes mellitus with **1 or more** of the following:
 - Labile diabetes mellitus with documented life-threatening hypoglycemic unawareness and/or frequent hypoglycemic episodes despite optimal medical management, Clark Hypoglycemic Score ≥ 4 (see Appendix C)
 - Physical or psychological inability to safely administer exogenous insulin
 - Type 2 diabetes mellitus with **1 or more** of the following:
 - Labile diabetes mellitus with documented life-threatening hypoglycemic unawareness despite optimal medical management, Clark Hypoglycemic Score ≥ 4 (see Appendix C)
 - Physical or psychological inability to safely administer exogenous insulin
 - Appropriate individuals will have **ALL** of the following:
 - 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
 - Left ventricular ejection fraction $\geq 40\%$ with no left ventricular hypertrophy
 - No history of malignancy (if there is a positive history of malignancy, a requirement of an oncology evaluation to determine status of disease has been performed.)
 - **Simultaneous kidney-pancreas transplants (SPK) or Pancreas after Kidney Transplant (PAK)** are considered medically necessary for FAMIS children and Cardinal members under 21 years when **ALL** of the following criteria are met:
 - Individual has type 1 or type 2 diabetes mellitus
 - Individual qualifies for kidney transplant.
 - Individual had a social and psychological evaluation and any identified issues have been addressed.
 - Individual has been evaluated and the procedure has been approved by the institutional transplant committee.
 - The criteria for covering a pancreas transplant alone are not applicable when a kidney is also being transplanted.
 - No history of major vascular events such as bilateral limb amputations and disabling CVA
 - Not actively smoking
 - Left ventricular ejection fraction $\geq 40\%$ with no left ventricular hypertrophy
 - No history of malignancy (if there is a positive history of malignancy, a requirement of an oncology evaluation to determine status of disease has been performed.)
 - Non-correctable coronary artery disease
 - **Retransplantations** is usually due to non-function of the grafted organ(s), chronic rejection, and chronic allograft pancreatitis.

Solid Organ transplantations are considered **contraindicated and/or not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Active substance use disorders
- Active untreated or untreatable malignancy
- Adult patients with known heart disease including, but not limited to, heart failure, cardiomyopathy and coronary artery disease require cardiology consultation and completion of consultant's recommendations, if any.
- Allogeneic islet cell transplantation
- Gastrointestinal (GI) clearance may be indicated in patients with a history of complicated or active GI disorders.

- If applicable, individuals 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.
- Inactive alcohol and/or substance abuse (alcohol, crystal meth, heroin, cocaine, methadone, and/or narcotics, etc.) is not a contraindication
- Infections:
 - Systemic or uncontrolled infection including sepsis
- Irreversible, severe brain damage
- Need for possible substance abuse needs to be addressed
- Pediatric patients should have a normal history and physical, or if there is any indication of abnormal cardiac function, cardiology evaluation should be obtained.
- Recreational or medicinal use of marijuana is not a contraindication
- Severe end-stage organ damage that would have an impact on patient survival
- Significant uncorrectable life-limiting medical conditions
- Uncorrectable pulmonary disease. Pulmonary consultation and completion of consultant's recommendations if any is required.
- While there is no evidence-based, optimal period of sobriety, an attempt at a period of at least 90 days abstinence is expected. This would allow sufficient clinical improvement which may, in turn, avert the need for transplantation. See the organ-specific transplant sections below for additional information.
- Xenologous (also known as Heterologous)

Document History:

Revised Dates:

Reviewed Dates:

Effective Date: 5/1/2025

Coding:

Medically necessary with criteria:

Coding	Description
44132	Donor enterectomy (including cold preservation), open; from cadaver donor
44133	Donor enterectomy (including cold preservation), open; partial, from living donor
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44137	Removal of transplanted intestinal allograft, complete
S2053	Transplantation of small intestine and liver allografts
S2054	Transplantation of multivisceral organs
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
48554	Transplantation of pancreatic allograft

0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed;
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed;
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open
S2102	Islet cell tissue transplant from pancreas; allogeneic
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy

Considered Not Medically Necessary:

Coding	Description
	None

The preceding codes for treatments and procedures applicable to this policy are included above for informational purposes only. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy.

Policy Approach and Special Notes: *

- Coverage:
 - See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to products:
 - Policy is applicable to Sentara Health Plan Virginia Medicaid products.
- Authorization requirements:
 - Pre-certification by the Plan is required.
- Special Notes:
 - Medicaid
 - 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.
 - Service authorization requests must be accompanied by sufficient clinical records to support the request. Clinical records must be signed and dated by the requesting provider withing 60 days of the date of service requested.

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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Keywords:

small bowel transplant, isolated small bowel, combined small bowel/liver, and multivisceral transplant, (ITx), PANCREAS TRANSPLANTATION (PTx), cardiopulmonary transplantation, Solid Organ Transplantations.