

Policy Key: Pancreatic Transplants

TriWest Clinical Operations – TRICARE West Region

SCOPE

This Policy Key provides criteria to use during medical necessity review for the following transplants involving the pancreas: Simultaneous Pancreas-Kidney (SPK), Pancreas-After-Kidney (PAK), Pancreas-Transplant-Alone (PTA), and Pancreatic Islet Cell Transplantation when performed at a Medicare-approved pancreatic transplantation center.

NOT COVERED [1]

- Expenses waived by the transplantation center (e.g., beneficiary/sponsor not financially liable)
- Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program, unproven procedure)
- Administration of an unproven immunosuppressant drug that is not United States (U.S.) Food and Drug Administration (FDA) approved or has not received TRICARE approval as an appropriate “off-label” drug indication
- Pre- or post-transplantation nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members)
- Organ donor transportation
- Autologous islet cell transplantation, when used alone, and allogeneic islet cell transplantation for the treatment of diabetes mellitus
- SPK, PAK, and PTA are not covered when the any of the following contraindications exist:
 - Significant systemic or multisystemic disease (other than pancreatic-renal dysfunction) which limits the possibility of full recovery and may compromise the function of the newly transplanted organs
 - Active alcohol or other substance abuse
 - Malignancies metastasized to or extending beyond the margins of the kidney and/or pancreas
 - Significant coronary artery disease

COVERAGE CRITERIA [1]

Simultaneous Pancreas-Kidney (SPK) and Pancreas-After-Kidney (PAK)

- **Medical Director** may approve when **ALL** the following are met: [1]
 - Concomitant, Type I Diabetes Mellitus that is resistant to exogenous therapy and endstage chronic renal disease

- Have exhausted more conservative medical and surgical treatments for Type I Diabetes Mellitus and renal disease
- Have a realistic understanding of the range of clinical outcomes that may be encountered
- Plans for long-term adherence to a disciplined medical regimen are feasible and realistic

Pancreas-Transplant-Alone (PTA)

- **Medical Director** may approve when **ALL** the following conditions are met: ^[1]
 - Labile Type I Diabetes Mellitus
 - Patients with diabetes must be beta cell autoantibody positive; **or**
 - Patients must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than or equal to 225 mg/Dl.
 - Patients must have a history of medically uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness, recurring severe ketoacidosis, or recurring severe hypoglycemic attacks.
 - Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically recognized advanced insulin formulations and delivery systems.
 - Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression.
 - Patients must otherwise be a suitable candidate for transplantation.

Autologous Pancreatic Islet Cell Transplantation

- **Medical Director** may approve as an adjunct to a total or near total pancreatectomy for the treatment of chronic pancreatitis.

General Coverage Information. ^[1]

The following services and supplies related to SPK, PAK and PTA are covered:

- Evaluation of a potential candidate's suitability for SPK, PAK and PTA whether or not the patient is ultimately accepted as a candidate for transplantation
- Pre- and post-transplantation inpatient hospital and outpatient services
- Surgical services and related transplantation team pre- and postoperative services
- The donor acquisition team, including the transportation costs to the donor organ location and team and donated organ transportation to the transplantation center location

- Maintenance of the donor organ viability after all existing legal requirements for the donor organ excision have been met
- Donor costs except transportation
- Blood and blood products
- FDA-approved immunosuppression drugs to include off-label uses when reliable evidence documents that the off-label use is safe, effective, and in accordance with the national standards of practice in the medical community (proven). Mycophenolate mofetil (CellCept) and tacrolimus (PROGRAF) for the prophylaxis of organ rejection in patients receiving SPK, PAK, and PTA are covered
- Transplantation procedure complications, including inpatient care, infection management, and rejection episodes
- Periodic evaluation and assessment of the successfully transplanted patient
- Hepatitis B and pneumococcal vaccines for patients undergoing transplantation
- Deoxyribonucleic Acid-Human Leucocyte Antigen (DNA-HLA) tissue typing determining histocompatibility
- Patient transportation by air ambulance and certified life support attendant services

Policy Considerations/Medical Claims Review ^[1]

- For beneficiaries who fail to obtain preauthorization for SPK, PAK, and PTA, benefits may be extended if the services or supplies otherwise would qualify for benefits if preauthorization had been obtained.
- If preauthorization is not received, the appropriate preauthorizing authority is responsible for reviewing the claims to determine whether the beneficiary's condition meets the transplant's clinical criteria. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and contractor authorization will be reimbursed only under POS rules.
- SPK, PAK, and PTA transplantations will be paid under the Diagnosis Related Group (DRG)
- Donor organ and transplant team transportation claims shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.
- Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplant center in the name of the TRICARE patient.
- Acquisition and donor costs are not considered to be components of the services covered under the DRG. These costs must be billed separately on a standard Centers for Medicare and Medicaid Services (CMS) 1450 UB-04 claim form in the TRICARE patient's name.
- When a properly preauthorized transplant candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organs are found not suitable or other circumstances which prohibit the transplant from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.



- SPKs, PAKs, or PTAs performed on an emergency basis in an unauthorized renal transplant facility may be cost-shared only when the following conditions have been met:
 - The unauthorized center must consult with the nearest center that is TRICARE- or Medicare-certified renal transplantation center regarding the transplantation case
 - It must be determined and documented by the transplant team physician(s) at the approved center that the patient transfer (to the approved center) is not medically reasonable, even though transplantation is feasible and appropriate.
- The contractor shall reimburse charges for the services on a Point of Service (POS) basis, if TRICARE Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and contractor authorization. Special cost-sharing requirements apply to POS claims.

DEFINITIONS

NA

CODES

CPT 38221, 48160, 48554

REFERENCES

[1] TRICARE Policy Manual 6010.63-M, April 2021, Change 17 (September 20, 2024), Chapter 4, Section 24.7, Simultaneous Pancreas-Kidney (SPK), Pancreas-After-Kidney (PAK), and Pancreas-Transplant-Alone (PTA), and Pancreatic Islet Cell Transplantation,
https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C4S24_7.html