Chapter 4 Section 24.7

Simultaneous Pancreas-Kidney (SPK), Pancreas-After-Kidney (PAK), And Pancreas-Transplant-Alone (PTA), And Pancreatic Islet Cell Transplantation

Issue Date: February 5, 1996
Authority: 32 CFR 199.4(e)(5)

Revision:

1.0 CPT PROCEDURE CODES

48160, 48550 - 48556

2.0 POLICY

2.1 Benefits are allowed for SPK transplantation, PAK transplantation, and PTA.

2.1.1 A TRICARE Prime enrollee must have a referral from their Primary Care Manager (PCM) and an authorization from the contractor before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and contractor authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and contractor authorization. Contractors shall reimburse charges for the services on a Point of Service (POS) basis. Special cost-sharing requirements apply to POS claims.

2.1.2 For Standard and Extra patients residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director or other designated utilization staff.

2.2 SPK and PAK are covered when the transplantation is performed at a Medicare-approved renal transplantation center, for patients who:

2.2.1 Are suffering from concomitant, Type I Diabetes Mellitus that is resistant to exogenous therapy and end stage chronic renal disease; and

2.2.2 Have exhausted more conservative medical and surgical treatments for Type I Diabetes Mellitus and renal disease.

2.2.3 Have a realistic understanding of the range of clinical outcomes that may be encountered.

2.2.4 Plans for long-term adherence to a disciplined medical regimen are feasible and realistic.

2.3 PTA is covered when performed at a Medicare approved renal transplantation center.

2.3.1 For patients who are suffering from labile Type I Diabetes Mellitus:

- Patient with diabetes must be beta cell autoantibody positive; or
- Patient 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;

2.3.2 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 or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;

2.3.3 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;

2.3.4 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;

2.3.5 Patients must otherwise be a suitable candidate for transplantation.

2.4 Services and supplies related to SPK, PAK, and PTA are covered for:

2.4.1 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.

2.4.2 Pre- and post-transplantation inpatient hospital and outpatient services.

2.4.3 Surgical services and related pre- and postoperative services of the transplantation team.

2.4.4 The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

2.4.5 The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

2.4.6 Donor costs.

2.4.7 Blood and blood products.

2.4.8 U.S. Food and Drug Administration (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.

2.4.9 Complications of the transplantation procedure, including inpatient care, management of infection and rejection episodes.

2.4.10 Periodic evaluation and assessment of the successfully transplanted patient.

2.4.11 Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

2.4.12 Deoxyribonucleic Acid-Human Leucocyte Antigen (DNA-HLA) tissue typing in determining histocompatibility.

2.4.13 Transportation of the patient by air ambulance and the services of a certified life support attendant.

2.5 Autologous pancreatic islet cell transplantation as an adjunct to a total or near total pancreatectomy for the treatment of chronic pancreatitis is covered (Current Procedural Terminology (CPT) procedure code 48160).

3.0 POLICY CONSIDERATIONS

3.1 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 but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the SPK transplantation benefit. 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.

3.2 Benefits for SPK, PAK, or PTA transplantation will only be allowed for transplants performed at a Medicare-approved renal transplantation center.

3.3 SPK, PAK, and PTA transplantations shall be reimbursed under the assigned Diagnosis Related Group (DRG).

3.4 Claims for transportation of the donor organ and transplantation team 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.

3.5 Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the TRICARE patient.

3.6 Acquisition and donor costs are not considered to be components of the services covered under the DRG and will be reimbursed based on billed charges. These costs must be billed separately on a standard Centers for Medicare and Medicaid Services (CMS) 1450 UB-04 claim form in the name of the TRICARE patient.

3.7 When a properly preauthorized candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organ is 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.

3.8 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 Medicare-certified renal transplant center regarding the transplantation case; and

- It must be determined and documented by the transplant team physician(s) at the Medicare-approved renal transplantation center that transfer of the patient (to a Medicare-approved renal transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate.

4.0 EXCLUSIONS

4.1 SPK, PAK, and PTA are excluded when any of the following contraindications exist:

4.1.1 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.

4.1.2 Active alcohol or other substance abuse.

4.1.3 Malignancies metastasized to or extending beyond the margins of the kidney and/or pancreas.

4.1.4 Significant coronary artery disease.

4.2 The following are also excluded:

4.2.1 Expenses waived by the transplantation center (e.g., beneficiary/sponsor not financially liable).

4.2.2 Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

4.2.3 Administration of an unproven immunosuppressant drug that is not FDA approved or has not received TRICARE approval as an appropriate "off-label" drug indication.

4.3 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).

4.4 Transportation of an organ donor.

4.5 Autologous islet cell transplantation, when used alone, and allogeneic islet cell transplantation for the treatment of diabetes mellitus (CPT procedure codes 0141T - 0143T and HCPCS codes G0341 - G0343, S2102).

5.0 EFFECTIVE DATES

5.1 October 1, 1995, for SPK transplants.

5.2 January 1, 1996, for PAK and PTA transplants.

5.3 January 1, 2007, for autologous pancreatic islet cell transplantation as an adjunct to a total or near total pancreatectomy for treatment of chronic pancreatitis.

- END -