



Subject: *Simultaneous Pancreas-Kidney (SPK) Transplant*

Number: *200306-0010*

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Important note

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy & Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following website:

<http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

Overview

A pancreas transplant performed at the same time as or after a kidney transplant may be medically necessary for patients with specific diagnoses. These transplants are performed using a cadaver donor pancreas and either a cadaver or living – such as from a relative – donor kidney.

The focus of this policy is the **simultaneous pancreas-kidney (SPK) transplant**. There is a separate policy for the pancreas after kidney (PAK) transplant.

Policy and criteria

NOTE: These services require prior authorization by the Plan Medical Director.

When services are covered:

Simultaneous pancreas-kidney transplantation (SPK) is covered for end-stage renal disease due to diabetic nephropathy for patients who meet all the following guidelines, when no contraindications (listed below) are present:

- Insulin-dependent diabetes mellitus (IDDM); AND
- Age 18 to 55 years; AND
- End-stage renal disease (ESRD) and requires dialysis *or* is expected to require dialysis in the next 12 months; AND
- Creatinine clearance (Clcr) calculated by the Cockcroft-Gault formula of < 30 mL/min; AND
- Adequate social support

Note: The Cockcroft-Gault formula for calculation of Clcr is generally accepted as superior to actual measured creatinine clearance as determined by a 24-hour urine collection, due to inherent inaccuracies and collection difficulties.

Cockcroft-Gault Formula

Estimated creatinine clearance (mL/min) - males:
(140 - age) x weight (kg) plasma creatinine (mg/dl) x 72
Estimated creatinine clearance (mL/sec) - females:
0.85 (140 - age) x weight (kg) plasma creatinine (mg/dl) x 72

In addition, the member must have completed an evaluation and been accepted by the decision making entity at the FCHP designated transplant center.

SPK transplant may be covered for patients with one or more of the following **relative contraindications** if the physician requesting the transplant can document, in writing, that the potential benefits outweigh the risks. Relative contraindications to SPK transplantation include:

- Patients with body mass index (BMI) > 35
- Patients with chronic liver disease
- Patients with uncontrolled hypertension (target BP 135/85 or less).

Please refer to the **Transplant Policy** for additional information regarding covered and non-covered services.

When services are not covered:

We **do not cover** SPK transplantation when any of the following **contraindications** exist:

- Insufficient cardiac reserve, as evidenced by one or more of the following:
 - Stress thallium or persantine thallium, or other diagnostic test demonstrating significant uncorrectable coronary artery disease
 - Inadequate myocardial function by echocardiogram
 - Ejection fraction < 40%
 - Myocardial Infarction < 3 months ago
- Evidence of severe cerebrovascular or peripheral vascular disease (ischemic ulcers, dependent rubor, rest pain, or major limb amputation)
- Major psychiatric illness or non-compliance
- Ongoing substance abuse (alcohol, drug, or tobacco)
- Cancer (except non-melanoma skin) unless free of disease without recurrence for > 5 years
- Active, ongoing or recurrent infection(s)
- Malignancy
- Peptic ulcer disease
- Uncorrectable congenital anomalies
- History of multiple abdominal surgeries
- Inability to adhere to the regime necessary to preserve the transplant

We do not cover **pancreas retransplants after 2 or more prior failed pancreas transplants**, because there is inadequate scientific evidence regarding the health outcomes associated with subsequent pancreas transplants.

Products to which this policy applies:

- ⊕ Commercial Plan (Direct, Select & PPO Plans)
- ⊕ The Independent Plan
- ⊕ Fallon Flex
- ⊕ Major Medical
- ⊘ Medicare Plan – refer to CMS for policy and criteria.

Reference

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Approved by:

Dennis A. Batey, MD

Signature on file

Vice President and Chief Medical Officer

Date
