Subject: ***Pancreas After Kidney (PAK) Transplant***

Number: ***200306-0011***

Effective date: 08/11/2003
Revision date(s): 07/22/2003

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 after a kidney transplant may be medically necessary for patients with specific diagnoses. These transplants are performed using a cadaver donor pancreas and following the transplant of a cadaveric or living – such as from a relative – donor kidney.

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

Policy and criteria

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

When services are covered:
We cover sequential **pancreas after kidney (PAK) transplantation** for patients with insulin-dependent diabetes mellitus (IDDM) who meet ALL of the following conditions:

- Status post a successful kidney transplantation, as evidenced by the absence of significant chronic rejection on kidney transplant biopsy; AND
- Presence of stable kidney transplant function (creatinine clearance as calculated by the Cockcroft-Gault formula of 30 ml/min and the absence of significant proteinuria); AND
- Absence of any absolute contraindication (see below).

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:

$$\frac{0.85\,(140 - \text{age}) \times \text{weight (kg)}}{\text{plasma creatinine (mg/dl)} \times 72}$$

In addition, the member must have completed an evaluation and been accepted as a transplant candidate by the FCHP designated transplant center.

PAK transplant may 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** PAK 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.

References

1. AHCPR Publication No. 95-0065 of the US Dept. of Health and Human Services Publish Health Service Health Technology Assessment no. 4 August 1995, entitled *Simultaneous Pancreas-Kidney (SPK) and Sequential Pancreas-After-Kidney (PAK) Transplantation.*
2. American Diabetes Association. Pancreas transplantation for patients with type 1diabetes (Position Statement). Diabetes Care. 2003;26(Suppl 1):S120.
3. American Diabetes Association: Clinical Practice Recommendations 1997, Volume 20 Supplement 1, available at http://www.diabetes.org/diabetescare/supplement197/s54.htm
4. Cicalese L, Giacomoni A, Rastellini C, Benedetti E. Pancreatic transplantation: a review. Int Surg. 1999;84(4):305-312.
5. Elliott MD, Kapoor A, Parker MA, et al. Improvement in hypertension in patients with diabetes mellitus after kidney/pancreas transplantation. Circulation. 2001;104(5):563-569.
6. Friedman AL. Appropriateness and timing of kidney and/or pancreas transplants in type 1 and type 2 diabetes. Adv Ren Replace Ther. 2001;8(1):70-82.
7. Hricik DE. Kidney-pancreas transplantation for diabetic nephropathy. Semin Nephrol. 2000;20(2):188-198.
8. Humar A, Ramcharan T, Kandaswamy R, et al. Pancreas after kidney transplants. Am J Surg. 2001;182(2):155-161.
9. Humar A, Sutherland DE, Ramcharan T, et al. Optimal timing for a pancreas transplant after a successful kidney transplant. Transplantation. 2000;70(8):1247-1250.
10. Israni AK. Quality of life after transplantation for patients with diabetes and renal dysfunction. Transplantation. 2001;72(5):969-970.
11. Kaufman DB, Leventhal JR, Elliott MD, et al. Pancreas transplantation at Northwestern University. Clin Transpl. 2000;239-246.
12. Koznarova R, Saudek F, Hrachovinova T, et al. The quality of life of pancreas recipients with type-1 diabetes. Transplant Proc. 2001;33(1-2):1890.
13. Kronson JW, Gillingham KJ, Sutherland DE, Matas AJ. Renal transplantation for type II diabetic patients compared with type I diabetic patients and patients over 50 years old: a single-center experience. Clin Transplant. 2000;14(3):226-234.
14. Ojo AO, Meier-Kriesche HU, Arndorfer JA, et al. Long-term benefit of kidney-pancreas transplants in type 1 diabetics. Transplant Proc. 2001;33(1-2):1670-1672.
15. Pirson Y, Vandeleene B, Squifflet JP. Kidney and kidney-pancreas transplantation in diabetic recipients. Diabetes Metab. 2000;26 Suppl 4:86-89.
16. Porte D Jr, et al. Pancreas transplantation for patients with diabetes mellitus (Technical Review). Diabetes Care 15:16681672, 1992.
17. Pox C, Ritzel R, Busing M, et al. Combined pancreas and kidney transplantation in a lean type 2 diabetic patient. Effects on insulin secretion and sensitivity. Exp Clin Endocrinol Diabetes. 2002;110(8):420-424.
18. Robertson RP, Davis C, Larsen J, et al. Pancreas and islet transplantation for patients with diabetes (Technical Review). Diabetes Care. 2000;23:112-116.
19. Sutherland DE, Gruessner RW, Gruessner AC. Pancreas transplantation for treatment of diabetes mellitus. World J Surg. 2001;25(4):487-496.

Approved by: *Signature on File*

Dennis A. Batey, M.D., Vice President and Chief Medical Officer Date