|  |  |
| --- | --- |
| **TITLE:** Kidney-Pancreas Pre-Transplant: Selection Criteria for Pancreas and Kidney/Pancreas Transplantation | |
| **APPLICABLE FACILITIES:** (check all that apply)  □EUH **□**EUOSH □EWWH □EUHM □EJCH □ESJH □TEC □ESA □ERH | |
| **EFFECTIVE DATE:** 10/21/2020 | **ORIGINATION DATE:** 8/5/2006 |

**SCOPE:**

The Emory Transplant Center Kidney and Pancreas Transplant Program

**PURPOSE:**

According to CMS Conditions of Participation (CoP) for transplant centers, *COP 482.90: Patient and Living Donor Selection*, the kidney/pancreas transplant program must use written patient selection criteria in determining a patient’s suitability for transplantation. The Emory Kidney/Pancreas Transplant Program is committed to the application of consistent criteria in evaluating patients with organ failure to determine transplant candidacy.

**GUIDELINES:** All patients referred for primary or repeat pancreas or kidney/pancreas transplantation undergo a rigorous medical, psychological, and social evaluation by the transplant team and other specialty consultants as indicated. The medical evaluation includes a complete history and physical examination with radiologic and laboratory assessment to determine severity of the pancreas or kidney/pancreas disease and any co-morbidity factors. On the basis of this comprehensive evaluation, a decision is made by the multi-disciplinary kidney/pancreas transplant team regarding the advisability of pancreas or kidney/pancreas transplantation.

Consideration for candidacy for pancreas or kidney/pancreas transplant is based on specific program selection criteria. Candidates must have insulin-dependent diabetes mellitus and desire a pancreas or kidney/pancreas transplant.

Candidates are considered based on

1) the individual’s overall health and functional status (regardless of age)

2) sufficient family and social support systems

3) the ability to obtain transportation to and from the transplant center, and

4) the ability to obtain and take prescribed medications after transplant and to successfully manage the post-transplant treatment regimen.

**Additional Information**

Candidates must be determined to have insulin-dependent diabetes to receive a pancreas transplant and have a BMI of 30 or less. Patients with type II diabetes will be selected generally:

* if their insulin requirement is less than 75 units per day
* BMI must be ≤ 30 kg/m2​
* C-peptide will be used as an adjunct to determine degree of insulin resistance

Candidates with Type II diabetes will be evaluated by Emory endocrinologists that work closely with the pancreas transplant team.

Pancreas transplantation may be performed simultaneously with a kidney transplant (SPK), after a kidney transplant (PAK) or pancreas transplant alone (PTA). Candidates for a SPK will be on renal replacement therapy or have a measured or calculated creatinine clearance of 20 ml/min or less. Candidates for PAK will have had a previous renal transplant and have good function of the transplant as determined by a measured or calculated creatinine clearance of 40 ml/min or greater. Candidates for PTA should have good function of their native kidneys (creatinine clearance of 40 ml/min or greater) and be experiencing significant short term risk of morbidity or mortality from the diabetes despite excellent compliance with an optimized insulin regimen under the care of an endocrinologist. An example would be a patient that is experiencing frequent episodes of hypoglycemic unawareness.

**Selection Criteria:**

There are many situations in which pancreas or kidney/pancreas transplantation may not be appropriate. The following list is intended as guidance for appropriate patient referral:

**Absolute Contraindications**

1- Active infection. This may include bacterial, viral and/or fungal infections.

2- Previous aortofemoral graft reconstruction for peripheral vascular disease.

3- Severe mental disability without adequate social support to manage post-transplant regimen.

4- Severe irreversible extra-renal end-organ disease, such as respiratory disease, cardiac disease or hepatic disease.

5- Severe active vasculitis or other autoimmune disorders.

6- Current untreated malignancy other than non-melanoma skin cancer, including patients with recent metastatic disease.

7- Active drug abuse (cocaine, IV drugs, methamphetamines, alcohol, etc.)

8- Current use of tobacco products. Patients must be nicotine free for 6 months before being considered as a candidate for transplant.

9- General medical condition and/or functional status that makes the risk of transplant greater than the potential benefit.

10- Absence of psychosocial support

**Relative Contraindications**

1- Serious medical problems that may be reversible.

2- Organic neurological disorders, psychiatric disorders, and/or drug addiction that will, in our opinion, significantly impair the candidate’s ability to manage the post-transplant regimen.

3- Severe peripheral vascular disease.

4- Malignancy within the last two to five years other than non-melanoma skin cancers. Candidates with a previous malignancy will be evaluated individually based on surgery notes, pathology reports, and cancer treatment records.

5- Moderately severe or severe cardiac disease, including ischemic myocardial disease, congestive heart failure, valvular disease and myopathies.

6- Chronic active inflammatory or infectious diseases.

7- Obesity or malnutrition to the extent that this factor significantly impacts surgical risk and life expectancy.

8- Chronic upper respiratory disease.

9- Uncorrected lower urinary tract abnormalities.

10. Inability to provide adequate psychosocial support plan.

11. Inability to provide adequate financial plan for provision of medications and the costs associated with post-transplant care.

12. Failure to follow no show/cancellation policy.

13. Failure to complete required testing and/or transplant plan within program timeframe guidelines.

14. Non-adherence with dialysis and medical treatment regimen.

15. Failure to maintain contact with the transplant center.

**Timeframe for re-evaluation: see the Waitlist management policy**

**Alternative Therapy for Transplantation**

Potential therapies may include but are not limited to: hemodialysis and peritoneal dialysis. If you are diabetic you may benefit from insulin pump therapy.

**RELATED DOCUMENT(S)/LINK(S):**

**DEFINITIONS:** *(If applicable)*

BMI – Body Mass Index

SPK-Simultaneous Pancreas/Kidney Transplant

PAK-Pancreas After Kidney Transplant

PTA-Pancreas Transplant Alone

IV-Intravenous

**REFERENCES AND SOURCES OF EVIDENCE:**

1. Kasiske, B.L. and D. Klinger, Cigarette smoking in renal transplant recipients. J Am Soc Nephrol, 2000. 11(4): p. 753-9.

2. Biesenbach, G., et al., Impact of smoking on progression of vascular diseases and patient survival in type-1 diabetic patients after simultaneous kidney-pancreas transplantation in a single centre. Transpl Int, 2008. 21(4): p. 357-63.

3. Penno, G., et al., Independent correlates of urinary albumin excretion within the normoalbuminuric range in patients with type 2 diabetes: The Renal Insufficiency And Cardiovascular Events (RIACE) Italian Multicentre Study. Acta Diabetol, 2015. 52(5): p. 971-81.

4. Al-Qaoud TM, Odorico JS, Redfield RR 3rd. Pancreas transplantation in type 2 diabetes: expanding the criteria. Curr Opin Organ Transplant. 2018 Aug;23(4):454-460. doi: 10.1097/MOT.0000000000000553. PMID: 29916848.

5. Alhamad T, Kunjal R, Wellen J, Brennan DC, Wiseman A, Ruano K, Hicks V, Wang M, Schnitzler MA, Chang SH, Lentine KL. Three-month pancreas graft function significantly influences survival following simultaneous pancreas-kidney transplantation in type 2 diabetes patients. Am J Transplant. 2020 Mar;20(3):788-796. doi: 10.1111/ajt.15615. Epub 2019 Nov 1. PMID: 31553823.

**KEY WORDS:**

|  |  |
| --- | --- |
| **REVIEW/APPROVAL SUMMARY:** | |
| **APPROVAL BODY/BODIES:** Renal Transplant Leadership Group | |
| **REVIEW/REVISION DATES:** 12/15/06**,** 2/6/08, 2/1/2012, 3/15/11, 6/30/11, 2/1/1012, 3/16/2016, 10/12/2016 | **APPROVAL DATE:** 2/14/2018 |