The Transplant Institute METHODIST DALLAS **Methodist Dallas Medical Center**	**Title:** Medical Evaluation Policy for Potential Kidney and Pancreas Transplant Recipients **Section:** Kidney and Pancreas	**Effective Date:** 10/16/2015
Approved by: Richard Dickerman, M.D., Surgical Director, Kidney/Pancreas Transplant Jose Castillo-Lugo, M.D., Medical Director, Kidney/Pancreas Transplant Melody Holder, Director of Transplant Clinical Operations		**Revision Date(s):** 03/04/2016; 12/11/2018; 03/01/2020;02/09/2021; 09/2022;11/2022; 6/2023; 04/01/2025; 01/22/2026 **Next review Date:** 01/2029

Purpose: To describe the evaluation process of the potential kidney and pancreas transplant recipient

Policy: The evaluation of the potential kidney transplant recipient will be coordinated by Methodist Dallas Medical Center (MDMC). The medical evaluation may also include information obtained from other consultants and specialists. Documentation of the evaluation is maintained by MDMC.

Procedure:
The transplant coordinator to whom the patient is assigned will contact the patient, perform a prescreening interview and make arrangements for the patient to complete evaluation appointment.

1) Evaluation Criteria
   - Creatinine clearance: 20 ml per minute by eGFR, 24 hour urine collection or Glofil
   - Recipients with a BMI up to 35 will be considered depending on body habitus, fat distribution and surgeon discretion. Recipients with a BMI of 35+ will be considered with the recommendation of a transplant surgeon.
   - Recipients who are current smokers and have a history of diabetes, any cardiac or vascular events (MI's, PVD, carotid disease, amputations) or interventions (peripheral or cardiac angioplasties/stents, peripheral vascular bypass, etc) may be required to stop smoking prior to evaluation. The committee may require documented negative carboxyhemoglobin prior to beginning evaluation.

2) Exclusions
   - Active infection
   - Active malignancy or metastatic disease (see attached table; page 10)
   - Active Multiple Myeloma
   - Significant cardiovascular disease
   - Significant liver disease
   - Morbid obesity
   - Psychiatric disorders unresponsive to treatment
   - Noncompliance with medication and/or treatment regimen
   - Ongoing substance dependency or abuse.
   - Inadequate financial/social resources to manage post-transplant regimen
   - MDMC will not discriminate against an organ transplant recipient solely on the basis of an individual's disability

3) Standard Evaluation

- Patient education session. This includes information about transplantation, post-transplant care, complications and immunosuppressant therapy. . Patients and family will be given the opportunity to ask questions.
- Transplant nephrology consultation
- Transplant surgical consultation/screening
- Infectious Diseases consultation/screening
- Transplant social worker consultation
- Transplant dietitian consultation
- Two view chest x ray
- Complete abdominal sonogram
- Echocardiogram
- EKG
- TB skin, Quantiferon gold test or T spot
- CMP, phosphorus, CBC with differential, platelet count, Lipid profile, TSH
- Serologies to include: HIV, HCV Ab, HBsAg, HBcAb, HBsAb Quant, RPR, CMV IgG, VZV IgG, EBV IgG
- Measles (Rubeola) IgG, Rubella IgG, Mumps IgG
- C Peptide for all diabetics on insulin
- HbA1c at the time of eval if patient doesn't have one in the last 3 months
- PT/INR
- PTT
- ABO x 2 from two separate blood draws
- Tissue typing and PRA

4) Additional laboratory studies

- PSA for men (per 2020 ACS Guidelines)-

Risk Level	***PSA Frequency***
Average Risk	Annual screening starting at age 50
African Americans or patients with father/brother/son diagnosed with prostate cancer before age 65	Annual screening starting at age 45
Annual Screening Frequency	Q 2 yrs PSA <2.5 Yearly PSA >2.5-4 Urology consult PSA >4

- Hep C RNA if HCV positive
- Hep B DNA if HBcAb positive
- Patients with SLE: ANA, C3, C4, Total complement, Lupus anticoagulant, Ant -DNA, Anti-cardiolipin Ab, Protein C antigen, Protein S, total/free
- Additional testing for patients who have experienced recurrent episodes of access clotting within one year that is not related to mechanical obstruction, have a history of DVT's, PE's or multiple miscarriages: PT/PTT, AT-III functional, Lupus anticoagulant, Anti-cardiolipin Ab, Protein C antigen, Protein S, total/free, and Factor V Leiden.
- Serum oxalate for all patients with a history of calcium oxalate stones

5) Additional consultations/testing

Depending on the patient's age and current health status, some of the following consultations/testing may be required during the pre-transplant medical evaluation.

- CT abdomen/pelvis without contrast
  - Diabetes Mellitus Type I or Type II
  - Smoker > 10 years regardless of smoking cessation
  - Diabetes and history of smoking regardless of length of diagnosis/smoking cessation
  - Previous Transplant
  - Adult PKD
  - History of peripheral vascular disease
- Carotid Doppler studies on the following patients:
  - Found to have a carotid bruit
  - Have a history of TIA or CVA
- CT Angio with runoffs
  - Peripheral Artery Disease
  - Prior vascular issues
  - Amputations
- CT chest without contrast if 30 pack-year history of smoking
  (pack-year = 1 pack of cigarettes per day per year. One pack per day for 30 years or 2 packs per day for 15 years would both be 30 pack-years)

Cardiac Evaluation:

Patients who have the following risk factors will be scheduled for a perfusion stress test or stress echocardiogram cardiac consult. Testing from an outside source may be acceptable if within the past 12 months

One of the following:

- Current smoker
- Diabetes Mellitus
- Prior ischemic heart disease
- Abnormal echocardiogram
- RVSP >45
- Abnormal perfusion stress test
- Patients > 60 years
- History of heart disease
- Peripheral vascular or carotid disease

Or 2 of the following:

- Males >45 years
- Females>55 years
- Family history of ischemic heart disease in first degree relative
- Former smoker
- Hypertension
- LVH

Cardiac catheterization will be required:

- If stress test is positive
- At the discretion of the cardiologist based on patient's history and symptoms

G.I. Consultation:

- Patients with a history of peptic ulcer disease, Irritable Bowel Disease, colon problems
- A colonoscopy is required for patients 45 years and older.

Pulmonary Consultation:

- Patients with history of infectious lung disease, restrictive lung disease, COPD or abnormal chest imaging.

Infectious Diseases Consultation:

- Patients with a new finding of a positive TB test and clear CXR will require treatment, but can continue with evaluation and be listed. Treatment is for a total of 9 months and can be completed after the transplant. Patients with a history of positive TB test and clear CXR will not require treatment after transplant if they have previously been treated.
- Patients may be listed Status 7 when they begin treatment for TB and may be changed to Status 1 when confirmation of 28 days of treatment has been completed. Treatment is for a total of 9 months.

Hematology Consultation:

- Patients with history of hypercoagulation or other associated diseases

Oncology Consultation:

- Patients with history of malignancy

Dermatology Consultation

- Patients with history of skin cancers

GU Consultation:

- Patients with obstructive uropathy, reflux, recurrent urinary tract infections, or urinary tract diseases
- Male patients on dialysis for 5 years or longer and are anuric

Hepatology Consultation:

- Patients with evidence of chronic liver disease, cirrhosis, hepatitis B, hepatitis C or liver abnormalities

Psychological Consultation (By Transplant Psychologist):

- Concerns regarding the capacity for the provision of informed consent
- Concerns regarding the capacity for adherence to post- transplant
- immunosuppression and follow-up care
- Individuals with significant anxiety disorder, psychosis, substance abuse, severe personality disorder, or cognitive
- Psychiatric consult if recommended by the Transplant Social Worker, Transplant Psychologist or Selection Committee

Neurological Evaluation:

- Consultation for patients with history of TIA's, cerebrovascular disease, seizure disorder, or other neurological disease
- Patients will have to wait 3 months post TIA or 6 months post CVA to be active on list
- MRA of brain without contrast for patients with all PKD without prior MRA

Gynecological Consultation: per 2020 KDIGO Guidelines.

Risk Level	***Pap Smear Frequency***
Average Risk	Screening every 3 years age 21 - 65 with HPV test every 5 years
Over age 65	Normal tests for past 10 years, No further testing required
History of cervical pre cancer	Test every 3 years for 25 years (even if after age 65)*
Total hysterectomy with BSO (not for cancer)	Annual screening at Ob/Gyn discretion
History of cervical cancer or HIV	Ob/Gyn consult

**Per 2019 ASCCP Guidelines*

- Females 40 years and over or with any family history of breast cancer or ovarian cancer in a first degree relative will have mammogram within the past year.
- Exceptions to this will be based on the recommendations of the patient's gynecologist.

Medical evaluation for Simultaneous Pancreas/Kidney Transplant (SPK), Pancreas after Kidney Transplant (PAK), Pancreas Transplant Alone (PTA)

General Indications/Eligibility for SPK, PAK or PTA:

- Diabetes with:
  - C-Peptide of < 2 ng/ml or:
  - C-Peptide of > 2 ng/ml and a BMI of 30 or less
- 55 years of age or less for SPK/PAK transplants
- 56-60 years of age on an individual basis
- 55 years of age or less for PTA
- Adequate cardiopulmonary function
- Ability to follow strict post-transplant follow-up regimen
- PAK: Creatinine clearance of 40cc/min.
- PTA: Creatinine clearance of 60cc/min.

Contraindications for SPK, PAK or PTA:

- Same as for kidney only.
- BMI over 30
- Age over 50 years of age for PTA
- Evidence of significant cardiovascular disease
- Current smoker

Medical Evaluation for SPK, PAK or PTA:

- Basic medical evaluation/consultations required for kidney transplantation
- Cardiology catheterization
- Urodynamic studies
- Additional diagnostic tests may be requested on an individual basis following evaluation by the Transplant Surgeon and Transplant Nephrologist.

Medical Complications that could delay the Pre-Transplant Work-Up:

Coronary artery disease requiring intervention:

- Angioplasty: Patients will require the following waiting period before being transplanted:
  - Bare Metal Stent: 3 months
  - Drug Eluting Stent: 12 months
- Patients will not be cleared for transplant while on antiplatelet therapy except for aspirin or Plavix
- Psychological issues including substance abuse (requires random drug screens for 6 months or duration of time established by Transplant Committee), psychological counseling, and documentation of patient compliance (for varying periods of times)
- Patients with active immunologic disease (SLE, Wegener's, Goodpastures', etc.) will not be transplanted while the disease is active. This requires 10 mg a day, or less, of prednisone and other markers of activity as the committee may deem appropriate

Waitlist Management:

- RVSP >45, echocardiogram every 3 months unless otherwise recommended by cardiologist

Annual Update Testing on Patients on the Transplant Waiting List

Annual testing includes the following:

- Transplant nephrologist or Advanced Practice Provider evaluation
- Update of all labs obtained during initial evaluation (except CMV, EBV, VZV (if previously positive), HLA, ABO) TB skin test, Quantiferon Gold test or T spot
- Measles (Rubeola) IgG, Rubella IgG, Mumps IgG (once – if not done during evaluation)
- Chest x-ray
- Complete abdominal sonogram every two years
- EKG
- Echocardiogram
- Female cancer screening:

Gynecological Consultation: per 2020 KDIGO Guidelines.

Risk Level	***Pap Smear Frequency***
Average Risk	Annual screening every 3 years age 25-65 with HPV test every 5 years
Over age 65	Normal tests for past 10 years, No further testing required
History of cervical pre cancer	Test every 3 years for 25 years (even if after age 65)*
Total Hysterectomy with BSO (not for cancer)	Annual screening at Ob/Gyn discretion
History of cervical cancer or HIV	Ob/Gyn consult

**Per 2019 ASCCP Guidelines*

- Females 40 years and over or with any family history of breast cancer or ovarian cancer in a first degree relative will have mammogram within the past year.
- Exceptions to this will be based on the recommendations of the patient's gynecologist.

Cardiac evaluation:
Yearly perfusion stress test or stress echocardiogram on all diabetics or patients with known coronary artery disease.

Patients who had a previous positive stress test followed by a negative cardiac catheterization, non-diabetics and patients who are non- symptomatic will require perfusion stress test or stress echocardiogram every other year if they meet the following criteria:

- Current Smoker

Or 2 of the following:

- Males >45 years
- Females>55 years
- Family history of ischemic heart disease in first degree relative
- Former smoker
- Hypertension
- LVH

- Patients who are Hepatitis B and/or Hepatitis C positive will require annual hepatology follow up
- Repeat of a consultation specialty if indicated

- Reassessment by social worker yearly
- Reassessment by dietitian yearly if BMI > 35 or tests pre frail or frail. Every two years for all other patients

TABLE 13.

Recommendations for cancer screening in the general population and potential transplant candidates

Cancer	General population	Potential transplant candidates
Breast	• Women ages 40 to 49 should have the choice to start annual breast cancer screening if they wish to do so • Biennial mammography is recommended for women age 50 and above • Screening should continue as long as woman is in good health and is expected to live 10 more years or longer[362]	• As per general population[363]
Colorectal	• Biennial fecal immunochemical testing (FIT) is recommended for all people age 50 years and above. Those with positive FIT should have full examination of the colon, preferably by colonoscopy • Flexible sigmoidoscopy (every 5 or 10 years) may also be considered for people age 50 years and above • Screening can be stopped for people who are older than 75 years or with life expectancy less than 10 years	• As per general population[364,365]
Liver	• Annual liver ultrasound and alpha-fetoprotein screening for those with known cirrhosis	• As per general population (see Rec 11.1.4)
Cervical	• Papanicolaou (Pap) test is recommended for women starting at the age of 21 and screening should be done every 3 years. Alternately, screening using HPV testing should be done every 5 years up to age 65 years. Women older than 65 should talk to their doctors about whether or not they need to have regular cervical screening. The decision to stop is often based on a woman's history of having normal or negative Pap test results • Women who had a previous total hysterectomy (removal of the uterus, including the cervix) do not require routine Pap screen	• As per general population[366]
Lung	• Routine screening for lung cancer using chest radiography and low-dose computed tomography (LDCT) *is not recommended* for average risk individuals • However, there is some evidence to suggest annual screening for people at high risk of lung cancer using LDCT. Individuals at high risk are adults aged 55 to 80 years who have a smoking history of at least 30 pack-years and currently smoke or have quit within the past 15 years[367]	• LDCT of the chest may be recommended for individuals who are at high risk of lung cancer, including a prolonged heavy smoking history (see Rec 11.1.1.2)
Prostate	• Men between the ages of 55 to 69 can undergo periodic screening for prostate cancer using prostate specific antigen if they wish to do so after understanding risks and benefits • Clinicians should not screen men who do not express a preference for screening and screening should stop at the age of 70	• As per general population[368]
Kidney	• Routine screening for renal cell cancer is not recommended for average risk individuals	• Ultrasonographic screening of the native kidneys may be recommended for individuals who have a family history of renal cancer, a personal history of acquired cystic disease, analgesic nephropathy, long-term smoking and/or prolonged waiting time on dialysis[369] (see Rec 11.1.2)
Bladder	• Routine screening for bladder cancer is not recommended for average risk individuals	• Urine cytology and cystoscopies may be recommended for individuals who had been previously exposed to chemotherapeutic agents such as cyclophosphamide, regular users of compound analgesics and for heavy smokers (≥ 30 pack-year history) (see Rec 11.1.3)

Source: KDIGO Practice Guidelines April 2020

TABLE 14.

Recommended waiting times between cancer remission and kidney transplantation[91]

Breast	Early	At least 2 years
	Advanced	At least 5 years
Colorectal	Dukes A/B	At least 2 years
	Duke C	2-5 years
	Duke D	At least 5 years
Bladder	Invasive	At least 2 years
Kidney	Incidentaloma (< 3 cm)	No waiting time
	Early	At least 2 years
	Large and invasive	At least 5 years
Uterine	Localized	At least 2 years
	Invasive	At least 5 years
Cervical	Localized	At least 2 years
	Invasive	At least 5 years
Lung	Localized	2-5 years
Testicular	Localized	At least 2 years
	Invasive	2-5 years
Melanoma	Localized	At least 5 years
	Invasive	Contraindicated
Prostate	Gleason ≤6	No waiting time
	Gleason 7	At least 2 years
	Gleason 8-10	At least 5 years
Thyroid	Papillary/Follicular/ Medullary	
	Stage 1	No waiting time
	Stage 2	At least 2 years
	Stage 3	At least 5 years
	Stage 4	Contraindicated
	Anaplastic	Contraindicated
Hodgkin Lymphoma	Localized	At least 2 years
	Regional	3-5 years
	Distant	At least 5 years
Non-Hodgkin Lymphoma	Localized	At least 2 years
	Regional	3-5 years
	Distant	At least 5 years
Post-transplant lymphoproliferative disease	Nodal	At least 2 years
	Extranodal and cerebral	At least 5 years

Source: KDIGO Practice Guidelines April 2020