



| SOUTHERN REGION POLICY |

This policy was approved by MaineHealth - Maine Medical Center (MMC) includes all locations and departments therein and further referenced as the Southern Region.

Policy Title: *Inclusion and Exclusion Criteria for Kidney Transplantation*

Contact Department: *MaineHealth Transplant - Portland*

(Search words:)

MaineHealth - Maine Medical Center Locations:

<input checked="" type="checkbox"/> Portland Campus	<input type="checkbox"/> Biddeford Campus
<input type="checkbox"/> Brighton Campus	<input type="checkbox"/> Sanford Campus
<input type="checkbox"/> Scarborough Campus	<input type="checkbox"/> Ambulatory Practices

Purpose: To define the inclusion & exclusion criteria for kidney transplantation.

Definitions:

ESRD	End-stage renal disease
CSPH	Clinically significant portal hypertension
Exclusion Criteria	Conditions or characteristics that exclude a potential transplant recipient from receiving a kidney transplant
Inclusion Criteria	Requirements a potential transplant recipient must meet in order to be receive a kidney transplant
Transplant Listing	Adding a potential transplant recipient to the United Network for Organ Sharing (UNOS) national transplant waitlist

Policy:

Organ transplantation is associated with risks due to anesthesia, surgery and immunosuppression. It is our policy to offer transplants to those candidates most likely to benefit while minimizing the risk of adverse effects and poor outcomes. The Maine Transplant Program selection criteria are therefore defined below:

Indications for transplantation:

1. ESRD (on dialysis) or eGFR<20mls/min.

2. Patient understanding of the risks and benefits associated with ESRD treatment options including dialysis and transplantation
3. Patient understanding of the essential nature of long-term immunosuppressive medications and the associated risks of serious complications including infection, malignancy and cardiovascular disease (further characterized in the “Kidney Transplant Surgery Consent”)
4. COVID vaccination is highly recommended, but not required, prior to listing.

Absolute Contraindications:

1. Metastatic Cancer
2. Serious conditions unlikely to be improved by transplantation as life expectancy can be finitely predicted such as:
 - Congestive Heart Failure with EF<40%
 - Active coronary artery disease not amenable to revascularization
 - Advanced COPD (hypercarbia, FEV/FVC< 80% and FEV1 < 50%, Chronic O2 use)
 - Severe pulmonary hypertension
 - Cirrhosis with portal hypertension
 - Dementia
 - Physical disability sufficiently severe to require long term skilled nursing facility placement
3. Chronic liver disease as evidenced by:
 - Decompensated liver disease
 - i. Encephalopathy
 - ii. Coagulopathy: INR>1.5 (assuming not on vitamin K antagonist; e.g. Coumadin)
 - iii. Ascites (not applicable to peritoneal dialysis patients)
 - iv. History of variceal hemorrhage
 - Compensated liver disease with clinically significant portal hypertension (CSPH). CSPH is defined as having a hepatic vein pressure gradient (HVPG) > 10 mm Hg.
4. Ongoing or recurring infections
5. HIV/AIDS related complications
 - Untreated HIV viremia
 - CD4<200
 - AIDS defining diagnosis
6. Active substance abuse (see “Narcotics, Recreational Drug Use and Transplantation Policy”).
7. Demonstrated patient non-adherence as evidenced by:
 - Non-attendance at dialysis or clinic visits
 - Persistent, excessive fluid weight gain

- Persistent hyperphosphatemia (>7)
- Persistent hyperkalemia (>5.5)
- Persistent hyperparathyroidism (PTH>500)
- 8. Inability to tolerate immunosuppression
- 9. Morbid Obesity (BMI>37, see “Obesity Policy”)
- 10. Prior early graft failure from either:
 - Recurrence of a primary kidney disease or
 - De novo allograft disease associated with a high risk of graft failure.
- 11. Inadequate health care insurance
- 12. Inability to travel to and attend clinic after transplantation.
- 13. Non adherence with Transplant Program Vaccination Policy
- 14. Uncontrolled psychiatric disorders.

Modifiable risk factors to be addressed prior to transplantation:

1. Coronary Heart Disease – Minimum criteria include:
 - EF to exceed 40%
 - Asymptomatic
 - Revascularization as clinically indicated
 - Compliance with medical regimen
 - Tobacco cessation
2. Peripheral Vascular Disease – Minimum criteria include:
 - Free of active infection, ulceration and rest pain
 - Revascularization as clinically indicated
 - Tobacco cessation
3. Cerebrovascular Disease – Minimum criteria include:
 - Non critical carotid artery disease
 - Revascularization as clinically indicated
 - Tobacco cessation
4. Peptic Ulcer Disease – Minimum criteria include:
 - Asymptomatic
 - No recent bleeding (<6 months)
 - On PPI or H2 blocker therapy
5. Chronic Lung Disease – Minimum criteria include:
 - Needs to be supplemental O2 free
 - Negative CT chest if age>55 and tobacco use exceeded 30 pack years
 - FEV/FVC > 80% and FEV1 > 50%
 - Tobacco cessation

6. Chronic active hepatitis – Minimum criteria include:
 - No evidence of CSPH on transjugular liver biopsy with pressures
 - No evidence of hepatocellular carcinoma on imaging
 - Needs to be actively seeing hepatology
 - Needs to be adherent with regimen
 - Hepatitis B Viremia needs to be controlled with therapy
 - o HBV: (entecavir/tenofovir disoproxil fumarate/tenofovir alafenamide)
 - Hepatitis C treatment may be recommended either before or after transplantation
7. Malignancy – Minimum criteria include:
 - Needs to be in full remission confirmed with current appropriate imaging
 - Minimum duration depends on type of malignancy – refer to MTP policy “Malignancy Prior to Transplantation” for specific requirements
8. Obesity – Minimum criteria include:
 - BMI>30-37 is regarded as a risk factor for complications (see “Obesity Policy”).
 - Patient may be advised to reduce weight
 - May be an absolute contraindication if numerous other issues co-exist.
9. Physical Disability
 - Regarded as a risk factor for complications
 - The patient must be able to attend clinic post surgery
 - Rehabilitation may be indicated before a decision can be made about a debilitated individual’s candidacy for transplantation
10. Diabetes Mellitus – Goals include:
 - Needs to check finger stick sugars at least twice a day
 - HbA1c level less than 8%
 - Tobacco cessation
11. Psychiatric Disorders (defined by the presence of psychiatric diagnoses or Rx psychotropic medications) – Minimum criteria include:
 - Consultation with psychiatry at MMC is REQUIRED in order to manage peri-transplant issues
 - Symptoms must be adequately controlled with appropriate medication for at least 6 months
 - Patient must have an ongoing relationship with a local psychiatric care provider
 - Patient must be adherent to their psychotropic medications
12. Malnutrition – Minimum Criteria include:
 - Needs dietary intervention for Albumen < 3.5g/dl
 - Minimum Albumin to exceed 3g/dl

13. Dental Clearance – may be required when dental status poses risk for infection post-transplant

14. Sustained suboptimal adherence with CKD/ESRD care defined by the following parameters for 3 or more months:

- Uncontrolled Hyperparathyroidism defined as PTH>500ng/ml
- Uncontrolled hyperphosphatemia defined as Phos persistent >7 mg/dl
- Uncontrolled hyperkalemia defined as K persistently >5.5 meq/l
- Excessive fluid weight gain between dialysis treatments defined as >3kg wt gains
- Persistently uncontrolled hypertension defined as greater than 150/90 at then end of dialysis treatments
- Premature signing off dialysis treatments
- Dialysis non attendance

The individual risk factors described may increase the risk of complications, graft failure and death after transplantation although may not be permanent barriers to transplantation. Regardless, such issues need to be optimized prior to transplantation in order to enhance post transplant outcomes. The presence of multiple such risk factors may collectively exclude a patient from transplantation.

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Revision Date(s): *8/1/2022, 2/1/2024, 6/4/2024, 8/30/2024*

Approval Committee(s):

This policy has been approved by representatives of the Southern Region in attendance at the {name of council or committee} meeting on {mm/dd/yyyy}.

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Martin Moehlen, MD, MPH contributed to the review and revision of this policy as related to liver disease-specific criteria.

Addendum:

