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# Ontario's Referral and Listing Criteria for Adult Kidney Transplantation

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Version 4.0

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# Adult Kidney Transplantation Referral & Listing Criteria

## PATIENT REFERRAL CRITERIA:

The patient referral criteria are guidelines which a Health Care Provider would utilize to refer a patient to a transplant center for assessment. In general, pre-emptive kidney transplantation is the preferred form of renal replacement therapy and should be encouraged where feasible. Patients should be referred for evaluation by the transplant program once renal replacement therapy is expected to be required within the next 12 months. Patients already requiring dialysis support should be referred for transplant evaluation as soon as their medical condition stabilizes.

The criteria identified below are the agreed upon conditions for which a patient should be referred for a kidney transplant assessment.

- 1) **Chronic Kidney Disease:** Referral for kidney transplantation should be considered for patients with progressive Chronic Kidney Disease.
- 2) **End Stage Renal Disease (ESRD):** Referral for kidney transplantation should also be considered for patients with End Stage Renal Disease (ESRD).

In addition, referral for kidney transplant evaluation should be considered for patients only if the following requirements are met:

1. Absence of active malignancy (metastatic carcinoma)
2. Absence of a critical inoperable valve disease
3. Absence of active irreversible ischemic progressive heart disease
4. Absence of severe (LVEF < 20%) left ventricle dysfunction (unless possibly uremic in origin)
5. Patient has consented to transplant

## PATIENT LISTING INDICATIONS:

In general, listing for kidney transplantation may be considered for all patients with end-stage renal disease provided no absolute contraindications exist. Each patient is assessed individually for their suitability for kidney transplantation by the kidney transplant program. Eligibility should be determined on medical and surgical grounds and should not be based on social status, gender, race or personal or public appeal.

A patient who does not meet the criteria for transplantation should routinely be offered, or may request, a second opinion from an alternative program able to assess the relative risks and benefits of kidney transplantation.

The criteria identified below are the agreed upon conditions for which a patient may be eligible to be waitlisted for kidney transplantation in Ontario.

- 1) **Renal Function:** Patients may only be considered for pre-emptive kidney transplantation if the measured or calculated glomerular filtration rate is less than 15 mL/minute on two occasions *and* there is evidence of progressive and irreversible deterioration in renal function over the previous 6–12 months.

In the case where a recipient has a living donor, referral should occur earlier to allow sufficient time for evaluation.

## ABSOLUTE LISTING CONTRAINDICATIONS:

The following are conditions relating to the transplant candidate that constitute absolute contraindications to kidney transplantation. As such, they prevent a transplant from being done until the condition is resolved.

- 1) **Co-Morbidities:** Patients with any co-morbidity that decreases the likelihood of surviving 5 years post-transplant to below 50% or whom which the peri-operative risk is deemed to be unacceptably high by the evaluation team, are not candidates for kidney transplantation.
- 2) **Consent:** Patients who do not want a transplant should not be listed for kidney transplantation.
- 3) **Post-Transplant Care:** Patients with an inadequate or unsafe post-transplant care plan are not candidates for kidney transplantation.
- 4) **Psychosocial Considerations:** Patients with an acute or untreated psychotic illness, or that display social support/compliance issues that prohibit adherence to therapy (e.g. attendance for dialysis and compliance with medications) are not candidates for kidney transplantation. Kidney transplantation should be delayed until patients have demonstrated adherence to therapy for at least 6 months.
- 5) **Malignancy:** In general, patients with an active malignancy are not candidates for kidney transplantation. Kidney transplant candidates with a previous history of malignancy should be tumour-free before proceeding with transplantation. Specific contraindications include:
  1. **Breast Cancer:** Patients with advanced breast cancer (stage III or IV) should not undergo kidney transplantation.
  2. **Liver Cancer:** Kidney transplantation is generally not recommended for patients with liver cancer unless it is part of a treatment strategy that includes liver transplantation.
  3. **Active Multiple Myeloma:** Patients with active multiple myeloma should not undergo kidney transplantation, although patients with myeloma with the option for successful stem cell transplant may be considered.

Most renal transplant candidates with a history of malignancy should wait a period of time between successful treatment and transplantation. Patients who do not meet the following waiting period criteria are not eligible for kidney transplantation.

1. **Bladder Cancer:** Patients with bladder cancer must wait at least 2 years from successful treatment to renal transplantation, although superficial low-grade lesions may not require any waiting time.
2. **Breast Cancer:** Patients with breast cancer must wait at least 5 years from successful treatment to transplantation. Patients with early in situ (e.g., ductal carcinoma in situ) lesions may only require a 2-year wait.
3. **Cervical Cancer:** Patients with cervical cancer must wait at least 2 years from treatment to transplantation. Patients with in situ cervical lesions may proceed with transplantation before the 2 year wait period.
4. **Colorectal Cancer:** Patients with colorectal cancer must wait at least 5 years from successful treatment to transplantation. A shorter waiting time of 2–5 years may be sufficient in patients with localized disease.
5. **Hodgkin's Disease, Non-Hodgkin's Lymphoma, Post-Transplant Lymphoproliferative Disorder, or Leukemia:** Patients with these diseases must wait at least 2 years from successful treatment to transplantation.
6. **Lung Cancer:** Patients with lung cancer must wait at least 2 years from successful treatment to transplantation.

7. **Melanoma:** Patients with melanoma must wait at least 5 years from successful treatment to transplantation. Patients with in situ melanoma may be considered for transplantation after waiting at least 2 years.
  8. **Basal Cell Carcinoma of the Skin:** Patients do not require any waiting time after successful removal before proceeding with transplantation.
  9. **Squamous Cell Carcinoma of the Skin:** There is no firm recommendation on wait time.
  10. **Renal Cell Carcinoma:** Patients with renal cell carcinoma must wait at least 2 years from successful treatment to transplantation. Patients with small, incidental tumours may not require any waiting period. Patients with large or invasive or symptomatic tumours may require a waiting period of 5 years.
  11. **Wilms' Tumour:** Patients with Wilm's Tumour must wait at least 1 year from successful treatment to transplantation.
  12. **Testicular Cancer:** Patients with testicular cancer must wait at least 2 years from successful treatment to transplantation.
  13. **Thyroid Cancer:** Patients with thyroid cancer must wait at least 2 years from successful treatment to transplantation.
- 6) **Pulmonary Disease:** Patients who require home oxygen therapy, have uncontrolled asthma, or have severe cor pulmonale are not candidates for kidney transplantation. Patients with severe chronic obstructive pulmonary disease (COPD) – pulmonary fibrosis or restrictive disease with any of the following parameters are not candidates for kidney transplantations:
- Best forced expiratory volume in 1 s (FEV<sub>1</sub>) < 25% predicted value;
  - PO<sub>2</sub> room air < 60 mmHg with exercise desaturation, SaO<sub>2</sub> < 90%;
  - > 4 lower respiratory infections in the last 12 months; or
  - Moderate disease with evidence of progression.
- 7) **Cardiac Disease:** Patients with critical inoperable valve disease should not be considered for transplant. Patients with severe irreversible (non-uremic) cardiac dysfunction should not be listed for kidney transplantation alone, but selected patients may be candidates for combined heart–kidney transplants.
- All kidney transplantation candidates should be assessed for the presence of ischemic heart disease (IHD) before transplantation. The minimum required investigations include medical history, physical examination, electrocardiogram (ECG) and a chest radiograph. Kidney transplantation is contraindicated in patients with IHD in the following situations:
- Patients with progressive symptoms of angina;
  - Patients with a myocardial infarction within 6 months;
  - Patients without an appropriate cardiac workup; or,
  - Patients with severe diffuse disease, especially with positive non-invasive tests in whom intervention is not possible and in whom expected survival is sufficiently compromised so that transplantation is not reasonable.
- 8) **Peripheral Vascular Disease:** Patients with large uncorrectable abdominal aneurysms, severe occlusive common iliac disease, active gangrene or recent atheroembolic events are not candidates for kidney transplantation.
- 9) **Gastrointestinal Disease:** Patients with the following conditions are not candidates for kidney transplantation:
- Acute pancreatitis within 6 months;
  - Active inflammatory bowel disease; or,
  - Active peptic ulcer disease until disease is successfully treated.

## RELATIVE LISTING CONTRAINDICATIONS:

The following are conditions relating to the transplant candidate that constitute relative contraindications to kidney transplantation. While each patient is evaluated on an individual basis, the presence of one or more of the following may preclude acceptance as a candidate for kidney transplantation.

- 1) **Age and functional capacity:** Advanced age per se is not a contraindication to kidney transplantation. Each patient is evaluated on an individual basis according to their general condition and risk factors. However, transplant candidates should have a reasonable probability of surviving beyond current waiting times for transplantation, given the resources required to assess and maintain patients on the renal transplant waiting list.

Cognitive or neurodevelopmental delay is not an absolute contraindication to renal transplant.

- 2) **Weight:** Generally, patients weighing less than 10kg should not undergo transplantation.
- 3) **Cause of Kidney Disease:** Patients with evidence of kidney disease that may recur post-transplant and cause rapid/progressive loss of kidney function may not be considered for kidney transplantation.
- 4) **Psychosocial Considerations:** Cognitive impairment is not an absolute contraindication to kidney transplantation. However, particular care must be taken to ensure that informed consent can be obtained and that a support system is in place to ensure adherence to therapy and patient safety.

A history of psychiatric illness is not an absolute contraindication to kidney transplantation. Capacity should be evaluated when indicated.

Kidney transplantation should be delayed until the patient has demonstrated freedom from substance abuse for at least 6 months.

- 5) **Obesity:** Referrals will be accepted on patients with a Body Mass Index (BMI) of  $<35 \text{ kg/m}^2$ . Patients with a BMI  $>36 \text{ kg/m}^2$  will be evaluated on an individual basis by the transplant team.
- 6) **Systemic Diseases:** Systemic diseases leading to End Stage Renal Disease (ESRD) are usually not a contraindication to kidney transplantation; however, the presence and severity of extra-renal disease will often determine whether transplantation is an option.
- 7) **Infections:** Patients with the following infections may not be eligible for kidney transplantation:
  - Patients with active infection, whether of viral, bacterial or fungal origin.
  - Patients with chronic open infected wounds.

Patients meeting the following criteria may be considered for transplant:

1. Serostatus for cytomegalovirus and Epstein–Barr virus should be assessed before transplant but should not determine eligibility for transplantation.
2. All patients being assessed for kidney transplantation should be screened for HIV infection. HIV-infected patients with end-stage renal failure may be considered for kidney transplantation if they meet the following criteria:
  - Demonstrated adherence to a highly active anti-retroviral therapy (HAART) regimen;
  - Undetectable ( $< 50$  copies/mL) HIV viral load for  $> 3$  months;
  - Cluster of differentiation (CD4) lymphocyte count  $> 200/\text{mL}$  for  $> 6$  months;
  - No opportunistic infections;

- Willingness to use prophylaxis against cytomegalovirus infection (CMV), Herpes simplex virus, Pneumocystis carinii pneumonia and fungal infection;
- Freedom from neoplasia, except for treated basal or squamous cell carcinoma of the skin, in situ anogenital carcinoma (human papilloma virus-associated anal intraepithelial neoplasia), solid tumours treated with curative therapy and disease-free at 5 years;
- Kidney transplantation eligibility criteria are met.

**8) Pulmonary Disease:** Patients with moderate chronic obstructive pulmonary disease (COPD)–pulmonary fibrosis or restrictive disease with any of the following parameters may not be considered for kidney transplantation:

- Best Tiffeneau-Pinelli index ( $FEV_{1}$ ) 25–50% of predicted value;
- Partial pressure of oxygen ( $PO_2$ ) room air < 60–70 mmHg;
- Restrictive disease with exercise desaturation,  $SaO_2$  90%.

Patients should be strongly encouraged to stop smoking before kidney transplantation. Patients who continue to smoke may be eligible for kidney transplantation with full informed consent regarding their increased risk.

**9) Cardiac Disease:** All patients should be assessed for the presence of ischemic heart disease (IHD) before kidney transplantation. The minimum required investigations include medical history, physical examination, electrocardiogram (ECG) and a chest radiograph.

Patients with IHD should be eligible for kidney transplantation if they fall into one of the following categories:

- Low-risk asymptomatic patients;
- Asymptomatic patients with negative non-invasive testing;
- Patients who have undergone successful intervention; or
- Patients who on angiography have non-critical disease and are on appropriate medical therapy.

Left ventricular (LV) dysfunction is not necessarily a contraindication to kidney transplantation.

Uremic LV dysfunction may improve after transplantation, thus it is not necessarily a contraindication to wait listing.

**10) Cerebral Vascular Disease:** Kidney transplantation should be deferred in patients with a history of stroke or transient ischemic attack for at least 6 months following the event. The patient should be stable, fully evaluated and treated with risk-reduction strategies before kidney transplantation.

**11) Peripheral Vascular Disease:** The presence of pre-transplant peripheral vascular disease (PVD) is not an absolute contraindication to kidney transplantation. However, the risk of death is increased and the presence of PVD should be considered in the context of other comorbidities in determining eligibility for kidney transplantation.

**12) Gastrointestinal Disease:** The presence of asymptomatic cholelithiasis is not a contraindication to kidney transplantation. Patients with chronic pancreatitis in remission for less than 1 year may not be eligible for kidney transplantation.

**13) Liver Disease:** Patients who are hepatitis B surface antigen positive or hepatitis C antibody positive should be considered for transplantation. However, eligibility will depend on other considerations such as viral load and liver function and liver histology.

Transplant candidates with severe cirrhosis should not be considered for kidney transplantation alone, but may be considered for combined liver-kidney transplantation.

- 14) Genitourinary Disease:** A urologic cause of ESRD is not necessarily a contraindication to transplantation provided appropriate urinary tract drainage can be achieved. Transplantation is not contraindicated in patients with a dysfunctional bladder.
- 15) Hematologic Disorders:** The presence of thrombophilia, hypercoagulable state or cytopenias is not an absolute contraindication to kidney transplantation, but these conditions should be fully investigated.
- 16) Hyperparathyroidism:** Hyperparathyroidism is not an absolute contraindication to kidney transplantation, but should be fully investigated. Parathyroidectomy should be considered prior to kidney transplantation for those who have failed medical management or have severe, persistent complications of hyperparathyroidism.

# Multi-Organ Kidney Transplantation Referral & Listing Criteria

A multi-organ kidney transplant is defined as any cluster or combination of kidney with another organ (except kidney and pancreas), including staged kidney transplants. The referral and listing criteria will apply to all multi-organ patients, defined as:

1. **Kidney Cluster:** A patient who is activated on the wait list for a kidney and non-kidney organ(s) (heart, lung, liver, or small bowel) and receives all organs simultaneously from the same deceased donor.
2. **Kidney Combination:** A patient who is activated on the wait list for a kidney and non-kidney organ(s) (heart, lung, liver, or small bowel) and may receive each organ at different times from different donors.
3. **Staged-Combined Kidney:** A patient who is activated on a non-kidney organ wait list and receives a non-kidney organ transplant (heart, lung liver, or small bowel). These patients may be subsequently activated on the wait list for a kidney transplant once they recover from their non-renal organ transplant.

## PATIENT REFERRAL CRITERIA:

The patient referral criteria are guidelines which a Health Care Provider and kidney transplant programs would utilize to refer a patient to a multi-organ transplant center for assessment. Patients with chronic kidney disease and other non-renal disease may be referred for multi-organ kidney transplant. Patients who do not meet the criteria for kidney transplant alone may be referred for a multi-organ kidney transplant including, but not limited to, the following cases:

- Cystic fibrosis, advanced chronic obstructive pulmonary disease
- Patients with primary oxalosis, atypical hemolytic uremic syndrome, and other primary enzyme replacement in rare hereditary metabolic diseases.
- Portal hypertension and compensated cirrhosis with risk of decompensation at time of kidney transplant
- Polycystic liver and kidney disease with severe mass effect in the setting of acceptable synthetic function
- Cardiac amyloidosis

## PATIENT LISTING INDICATIONS:

In general, listing for multi-organ kidney transplantation may be considered for all patients with no absolute contraindications. Each patient is assessed individually for their suitability by kidney and multi-organ transplant programs. Eligibility should be determined on medical and surgical grounds and should not be based on social status, gender, race or personal or public appeal.

A patient who does not meet the criteria for multi-organ kidney transplantation should be offered, or may request, a second opinion from an alternative program able to assess the relative risks and benefits of transplantation.

The criteria identified below are the criteria for which a patient may be eligible to be waitlisted for a multi-organ kidney transplantation in Ontario.



- 1) **Renal Dysfunction:** Listing for multi-organ kidney transplantation may be considered for patients with the following renal function:

Time	On dialysis	GFR <30 mL/min, not on dialysis	GFR ≥30 mL/min
<1 month	Possibly eligible	Not currently eligible	Not currently eligible*
1 to <3 months	Possibly eligible	Possibly eligible	Not currently eligible*
≥ 3 month	Eligible	Possibly eligible	Not currently eligible*

\*See exceptions for staged-combined kidney transplant and paediatric patients below.

- 2) **Non-Reversible Kidney Injury:** For patients who are “possibly eligible” based on their level and duration of renal dysfunction, listing for transplant may be considered by establishing non-reversibility of kidney injury. The work-up for establishing the non-reversibility of kidney injury may include history and duration of chronic kidney disease, clinical optimization, renal ultrasound, urine electrolytes, and renal biopsy. Irreversible kidney damage may be established using the following renal biopsy criteria:

- Minimum sample adequacy including greater than 10 glomeruli from at least two cores with > 75% glomerulosclerosis and > 75% interstitial fibrosis.

In the event the kidney biopsy is not possible or results are inconclusive, history of CKD and other tests results may support the diagnosis of chronic kidney damage.

- 3) **Staged-Combined Kidney Transplant:** For patients who do not meet the renal dysfunction indications outlined above, listing for a staged-combined kidney transplant may be considered with the following conditions:

- Patients may be eligible when uncertainty exists as to the irreversibility of renal dysfunction.
- Patients may be eligible when expected physiological instability relating to the non-renal organ transplantation affecting potential recovery of the kidney function after transplantation.
- Patients may be eligible if there is a medically approved living donor available for either the kidney or liver transplant, where applicable.
- Patients may be eligible if DSA is detected against a donor in a patient who is on the wait list for a simultaneous multi-organ transplant.

Patients must meet at least one of the criteria to be eligible for staged kidney transplantation after the non-kidney organ is transplanted.

For patients who do not meet the listing indications, transplant programs may apply to the Kidney Special Case Committee for consideration.

### **ABSOLUTE LISTING CONTRAINDICATIONS:**

The following are conditions relating to the transplant candidate that constitute absolute contraindications to multi-organ kidney transplantation. As such, they prevent a transplant from being done until the condition is resolved.

- 1) **Non-Kidney Organ Transplant Criteria:** Patients who do not meet current listing eligibility criteria, including the perioperative mortality risk criteria as applicable, for liver, heart, lung, and small bowel transplant alone. This includes patients enrolled in a clinical trial for experimental extended eligibility of the non-kidney organ.

### **RELATIVE LISTING CONTRAINDICATIONS:**

The following are conditions relating to the transplant candidate that constitute relative contraindications to multi-organ kidney transplantation. While each patient is evaluated on an individual basis, these conditions may preclude acceptance as a candidate for multi-organ kidney transplantation.

- 1) **High Status Heart Transplant Candidates:** Patients who are wait listed as Status 4 on the heart transplantation list may be eligible for multi-organ kidney transplantation and will be reviewed on a case-by-case basis.

## Version Control:

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