



Trillium
Gift of Life
Network

Ontario's Referral and Listing Criteria for Pancreatic Islet Transplantation

Version 1.0

Trillium Gift of Life Network

Pancreatic Islet 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. The criteria identified below are the agreed upon conditions for which a patient should be referred for a pancreatic islet transplant assessment.

- 1) **Diabetes:** Referral for islet transplantation should be considered for the following patients:
 - Patients with prevalence of type 1 diabetes for at least 5 years with insulin dependence.
 - Patients with frequent episodes of hypoglycaemia with hypoglycaemia unawareness
 - Patients with uncontrolled, highly variable blood glucose despite optimal medical (insulin) therapy.

- 2) **Medical Suitability:** Referral for islet transplantation should be considered for patients only if the following requirements are met:
 - BMI < 30 kg/m²
 - Hemoglobin A1C > 6.5%
 - Absence of life threatening active malignancy or cancer within 5 years
 - Absence of HBV, HCV, or HIV infection
 - Absence of contraindications to immunosuppression
 - No evidence of significant liver disease or portal hypertension
 - Psychiatric stability

- 3) **Age:** Referral for islet transplantation should be considered only for patients greater than 18 years of age.

- 4) **Islet Transplant Alone (ITA):** Referral for islet transplantation alone should be considered for patients who meet the following criteria:
 - Proteinuria < 500 mg/day and eGFR > 90 ml/min/1.73m²

- 5) **Islet after kidney (IAK):** Referral for islet after kidney (IAK) transplantation should be considered for patients if they meet the additional criteria:
 - Proteinuria < 500 mg/day and eGFR > 60 ml/min/1.73m²
 - Patient has had more than 1 year following successful kidney transplant with stable renal function and without acute graft rejection

PATIENT LISTING INDICATIONS:

In general, listing for pancreatic islet transplantation may be considered for all patients with no absolute contraindications. Each patient is assessed individually for their suitability for islet transplantation by their 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.

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

- 1) **Diabetes:** Patients may only be considered for islet transplantation if they all of the following criteria:
 - Uncontrolled and unstable type 1 diabetes for at least 5 years *and*
 - There is evidence of insulin-dependence *and*
 - Hypoglycaemic unawareness.

- 2) **Medical Suitability:** Patients may only be considered for pancreatic islet transplantation if the following requirements are met:
 - Presence of hemoglobin A1c > 6.5%
 - Evidence of excessive surgical risk for whole-organ pancreas transplantation
- 3) **Islet Transplant Alone (ITA):** Patients may only be considered for islet transplantation alone if they meet the following criteria:
 - Proteinuria < 500 mg/day and eGFR > 90 ml/min/1.73m²
- 4) **Islet after kidney (IAK):** Patients may only be considered for islet after kidney (IAK) transplantation if they meet the following criteria:
 - Proteinuria < 500 mg/day and eGFR > 60 ml/min/1.73m²
 - Patient has had more than 1 year following successful kidney transplant with stable renal function and without acute graft rejection.

ABSOLUTE LISTING CONTRAINDICATIONS:

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

- 1) **Age:** Patients under the age of 18 are not candidates for islet transplantation.
- 2) **Consent:** Patients who do not want a transplant are not candidates for islet transplantation.
- 3) **Malignancy:** Patients with an active malignancy or cancer within 5 years are not candidates for pancreatic islet transplantation. Pancreatic islet transplant candidates with high risk of return of malignancy are not candidates for pancreatic islet transplantation.
- 4) **Pregnancy:** Patients who are pregnant at the time of transplant or actively trying to become pregnant are not candidates of islet transplantation.
- 5) **Infections:** Patients with the following conditions are not eligible for transplantation:
 - Active infection, whether of viral, bacterial or fungal origin, at the time of transplant;
 - Untreated HBV, HCV, or HIV.
- 6) **Immunosuppression:** Patients with a contraindication to immunosuppression therapy are not candidates for transplant.
- 7) **Other Medical Conditions:** Patients with evidence of significant cardiac, pulmonary, liver, renal and/or hematologic disease or organ failure not amenable to treatment and/or organ transplant are not candidates for islet transplantation.

Patients with chronic pancreatitis are not candidates for islet transplantation.

- 8) **Psychosocial Considerations:** Patients with the following conditions are not candidates for islet transplantation:
 - A failed psychiatric transplant assessment
 - Failed social work assessment

- Lack of confidence in adherence to post-transplant care.
- Patients who actively smoke.

RELATIVE LISTING CONTRAINDICATIONS:

The following are conditions relating to the transplant candidate that constitute relative contraindications to pancreatic islet 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 pancreatic islet transplantation.

- 1) **Weight:** Patients with a BMI >30 kg/m² will be evaluated on an individual basis by the transplant team.
- 2) **Insulin Resistance:** Patients with insulin use of more than 0.9 units/kg/day may not be considered for pancreatic islet transplantation.
- 3) **Medical Therapy:** Patients with contra-indication to anti-coagulation may not be considered for pancreatic islet transplantation.
- 4) **Diabetes:** Patients with prevalence of type 2 diabetes may not be considered for pancreatic islet transplantation.

VERSION CONTROL

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