

OPTN/UNOS Policy Notice

Proposal to Change Waiting Time Criteria for Kidney-Pancreas Candidates

Sponsoring Committee:	Pancreas Transplantation Committee
Policy/Bylaws Affected:	11.3.B (Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old) and 11.3.D (Waiting Time Assignments for Kidney, Kidney-Pancreas, Pancreas, and Islet Candidates)
Public Comment:	January 22 - March 23, 2018
Board Approval Date:	June 12, 2018
Effective Date:	Pending implementation and notice to OPTN members

Problem Statement

Kidney-pancreas (KP) waiting time criteria that restricts access for certain candidates with high body mass index (BMI) and high C-peptide care clinically unnecessary and unfair. The criteria involve a complex calculation of the maximum BMI which is confusing and undermines transparency. And, because minority populations comprise a greater proportion of high BMI, high C-peptide candidates, these populations are more affected by the waiting time criteria. Waiting time is an important part of pancreas allocation, so the criteria may also limit access to transplantation for some clinically suitable candidates.

Summary of Changes

The changes remove the criteria that restrict access to accruing waiting time for high BMI, high C-peptide candidates. Candidates still have to be registered for a kidney-pancreas, meet kidney waiting time criteria, and must be on insulin.

What Members Need to Do

Transplant hospitals will need to educate staff regarding this change in policy so that staff is aware of the changes to KP waiting time criteria. This may affect their procedures regarding candidate recruitment and listing.

For OPOs, the potential for an increase in the number of pancreata recovered could impact the budget process, but not substantially.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (example).

11.3.B Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old

If a kidney-pancreas candidate is 18 years or older on the date the candidate is registered for a kidney-pancreas, then the candidate begins to accrue waiting time once the candidate has met all of the following conditions:

1. The candidate is registered for a kidney-pancreas.
2. The candidate qualifies for kidney waiting time according to *Policy 8.4: Waiting Time*.
3. The candidate is on insulin, ~~meets at least one of the following criteria:~~
 - a. ~~Is on insulin and C-peptide less than or equal to 2 ng/mL~~
 - b. ~~Is on insulin and C-peptide greater than 2 ng/mL and has a body mass index (BMI) less than or equal to the maximum allowable BMI.~~

Once a kidney-pancreas candidate begins to accrue waiting time, the candidate will remain qualified for waiting time, ~~unless the candidate was registered for a kidney-pancreas prior to implementation of this policy. A candidate who was registered for a kidney-pancreas, and accrued waiting time prior to implementation of this policy, will remain qualified if the candidate qualifies for kidney waiting time according to *Policy 8.4: Waiting Time*.~~

~~The maximum allowable BMI, for accruing waiting time, for a kidney-pancreas candidate, who is at least 18 years old at the time of kidney-pancreas registration, is 28 kg/m². Every six months, the OPTN Contractor will determine the percent of kidney-pancreas candidates that meet criterion 3.b above. The OPTN Contractor will then modify the maximum allowable BMI according to *Table 11-1* below:~~

Table 11-1: Maximum Allowable BMI

If the percent of active kidney-pancreas candidates that meet criterion 3.b:	Then the OPTN Contractor will:
Is greater than 15% nationally	Reduce the maximum allowable BMI by 2 kg/m²
Is less than 10% nationally	Increase the maximum allowable BMI by 2 kg/m²

~~The OPTN Contractor may not modify the maximum allowable BMI to exceed 30 kg/m². If the OPTN Contractor modifies the maximum allowable BMI, it must publish the modification and notify all kidney programs and pancreas programs.~~

~~Once a kidney-pancreas candidate qualifies for waiting time, the candidate will remain qualified for waiting time regardless of any changes to the maximum allowable BMI.~~

~~For candidates who qualify for kidney-pancreas waiting time, waiting time will begin when the candidate qualifies for waiting time according to this Policy. Transplant programs must document when and how a kidney-pancreas candidate qualified for waiting time.~~

11.3.D Waiting Time Assignments for Kidney, Kidney-pancreas, and Islet Candidates

The OPTN Contractor may assign multi-organ candidates waiting time from one waiting list to another waiting list according to *Table 11-2* below.

Table 11-21: Waiting Time Assignments for Multi-organ Candidates

From this registration:	To this registration:
Kidney	Kidney-pancreas; if criteria in <i>Policy 11.43.B: Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old</i> are met.
Kidney	Pancreas
Kidney-pancreas	Kidney
Kidney-pancreas	Pancreas
Pancreas	Pancreas-Islets ; if criteria in <i>Policy 11.3.D.i</i> below are met.
Pancreas-Islets	Pancreas; if criteria in <i>Policy 11.3.D.ii</i> below are met.

Waiting time accrued by an isolated pancreas candidate or an ~~an pancreas-islet~~ candidate while registered on the waiting list will not be assigned to the listing for a combined kidney-pancreas transplant or an isolated kidney transplant unless the candidate qualifies for a waiting time modification according to *Policy 3.7: Waiting Time Modifications*.

Waiting time accrued by an ~~an pancreas-islet~~ candidate while registered on the waiting list will not be assigned to the registration for a combined kidney-pancreas transplant or an isolated kidney transplant except as outlined in *Policy 3.7: Waiting Time Modifications*.

Additionally, a kidney-pancreas candidate who received a kidney transplant and subsequently registered on the pancreas or ~~pancreas-islet~~ waiting list will be assigned waiting time beginning on the *earliest* of the following dates:

1. The date the candidate registered for a pancreas transplant.
2. The date the candidate registered for a kidney-pancreas transplant.
3. The date the candidate began accruing waiting time for a kidney-pancreas transplant.

11.3.D.i Criteria to assign Pancreas Waiting Time to Islet Waiting Time

Waiting time accrued by an isolated pancreas transplant candidate while registered on the waiting list will be assigned to the registration for ~~an pancreatic islet cell~~ transplant after consideration and approval of a request for transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that the transfer is reasonable and is in the candidate's best interest, and comply with other application requirements set by the Committee. These requests, along with decisions of the Pancreas Transplantation Committee, will be reported to the Board of Directors retrospectively.

11.3.D.ii Criteria to assign Islet Waiting Time to Pancreas

Waiting time accrued by an islet ~~cell~~-transplant candidate while registered on the waiting list will be assigned to the registration for an isolated pancreas transplant after consideration and approval of a request for transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that the transfer is reasonable and is in the candidate's best interest, and comply with other application requirements set by the Committee. These requests, along with decisions of the Pancreas Transplantation Committee, will be reported to the Board of Directors retrospectively.

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