

Notice of OPTN Policy Changes

Eliminate the Use of DSA and Region from Pancreas Allocation Policy

Sponsoring Committee:	Pancreas Transplantation Committee
Policies Affected:	<p><i>1.2: Definitions</i></p> <p><i>11.4.A: Kidney-Pancreas Allocation Order</i></p> <p><i>11.4.B: Pancreas Allocation When a Kidney is Unavailable</i></p> <p><i>11.4.C: Organ Offer Limits</i></p> <p><i>11.4.D: Blood Type for Kidney-Pancreas Allocation</i></p> <p><i>11.4.E: Sorting Within Each Classification</i></p> <p><i>11.4.F: Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m²</i></p> <p><i>11.4.G: Deceased Donors More than 50 Years Old or with a BMI Greater than 30 kg/m²</i></p> <p><i>11.5: Reallocation of Unsuitable Islets</i></p> <p><i>11.6: Facilitated Pancreas Allocation</i></p>
Public Comment:	August 2, 2019 – October 2, 2019
Board Approved:	December 3,, 2019
Effective Date:	Pending implementation and notice to OPTN members

Purpose of Policy Changes

This policy change removes DSA and region from pancreas allocation policy. The policy replaces DSA and region with a 250 NM fixed circle and adds proximity points to candidate's total allocation scores.

Proposal History

This proposal began following the OPTN Board of Directors' 2018 directive that organ-specific committees remove DSA and region from allocation policies. The OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee formed a "KP Workgroup" to gather evidence and produce a proposal for Board consideration. The Workgroup produced a concept paper for the OPTN Spring 2019 Public Comment period. The Committee considered the community feedback, which informed more evidence gathering to produce a formal proposal for the OPTN Fall 2019 Public Comment period. The Committees again considered the community feedback to produce the final proposal for Board consideration in December 2019. The Board approved these policy changes on December 3, 2019.

Summary of Changes

This policy removes DSA and Region as units of allocation in pancreas policy. Allocation will instead have a first unit of a 250 nautical mile (NM) fixed-distance circle with the donor hospital at its center.

Additionally, this policy adds a candidate allocation score that includes points based on proximity of the candidate's transplant hospital of registration to the donor hospital. Candidates inside the circle can receive a maximum of 2 proximity points. Proximity points decrease linearly out to the 250 NM circle, where a candidate would receive no additional proximity points.

If allocation moves outside of the 250 NM circle, proximity points are then awarded to candidates outside of that circle. Candidates outside of the circle can receive a maximum of 4 proximity points, depending on the proximity of their center of listing to the donor hospital. As with proximity points inside the circle, proximity points outside the circle decrease in a linear fashion, out to 2500 NM away from the donor hospital. Proximity points only prioritize candidates within their classification, and so proximity points alone could not prioritize a candidate that is registered outside of the circle before a candidate that is inside the circle.

This policy also changes to facilitated pancreas placement to make it consistent with the changes to allocation. Specifically, pancreas programs will now qualify if they perform at least two pancreas transplants from further than 250 NM from the pancreas program in the previous two years. OPOs will only have access to facilitated allocation after all offers made to candidates registered at transplant programs within 250 NM of the donor hospital have been declined.

Implementation

Transplant Hospitals

As a result of the elimination of DSA as a unit of allocation, transplant hospitals will receive offers from OPOs they may not have worked with previously. Transplant hospitals will need to develop these relationships for future organ acceptances. Furthermore, under the broadened relationships, transplant hospitals may need to adjust their operations to account for the practices of their new OPO partners, including how they communicate with one another.

The changes to pancreas distribution may also impact overall transplantation program costs, as broader distribution may increase the number, distance, and time of additional pancreas fly outs.

OPOs

OPOs will continue allocating donor organs through the match runs. OPOs that will be working with transplant hospitals for the first time may want to consider developing working relationships to address issues such as sharing donor information and coordinating recoveries.

OPTN

Programming changes will be required for this proposal. This will be an "Enterprise" size effort in terms of IT implementation.

Changes will be made to the combined kidney-pancreas & pancreas allocation systems to remove DSA and Region and allocate using a 250 nautical mile circle with proximity points. In addition, classification titles in the pancreas and combined kidney-pancreas allocations will also be changed to remove references to "local" and "regional."

The OPTN will follow established protocols to inform members and educate them on any policy changes through Policy Notices and other communications. UNOS Professional Education will monitor for additional educational needs throughout the development of this proposal

Affected Policy Language

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

1.2 Definitions

~~Zero antigen 0-ABDR mismatch~~

A candidate is considered a ~~zero antigen 0-ABDR~~ mismatch with a deceased or living donor if *all* of the following conditions are met:

1. At least one donor antigen is identified for each of the A, B, and DR loci
2. At least one candidate antigen is identified for each of the A, B, and DR loci
3. The donor has zero non-equivalent A, B, or DR antigens with the candidate's antigens
4. The donor and the candidate have compatible or permissible blood types

In cases where a candidate or donor has only one antigen identified at an HLA locus (A, B, or DR), the antigens are considered to be identical at that locus. A ~~zero antigen 0-ABDR~~ mismatch may also be referred to as a zero mismatch or ~~0-ABDR~~ zero antigen mismatch.

Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets

11.2 Pancreas Allocation Score

Candidates receive an allocation score according to the total of all points assigned in Table 11-1.

Table 11-1: Allocation Points

<u>If the candidate:</u>	<u>Then the candidate receives this many points:</u>
<u>Is registered for pancreas or islet transplant</u>	<u>1/365 points for each day since candidate's registration date</u>
<u>Is registered for kidney-pancreas transplant and meets the qualifying criteria described in <i>Policy 11.3: Waiting Time</i></u>	<u>1/365 points for each day since meeting the qualifying criteria in <i>Policy 11.3: Waiting Time</i></u>
<u>Meets the qualifying criteria described in <i>Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital</i></u>	<u>See <i>Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital</i></u>

Table 11-2: Points for Allocation of Pancreas, Kidney-Pancreas, and Islets based on Proximity to Donor Hospital

For purposes of this section, distance is calculated in nautical miles between candidate’s hospital of registration and the donor hospital.

<u>If the candidate is:</u>	<u>Then the candidate receives this many points:</u>
<u>Registered at a transplant program that is 250 nautical miles or less away from the donor hospital</u>	$2 - \left[\left(\frac{2}{250 - 0} \right) \times distance \right]$
<u>Registered at a transplant program that is more than 250 nautical miles but 2,500 nautical miles or less away from the donor hospital</u>	$4 - \left[\left(\left(\frac{4}{2500 - 250} \right) \times distance \right) - \left(4 \times \frac{250}{2500 - 250} \right) \right]$
<u>Registered at a transplant program that is more than 2,500 nautical miles away from the donor hospital</u>	<u>0</u>

11.4.A Kidney-Pancreas Allocation Order

If a host OPO has both a kidney and a pancreas to offer for allocation, then the host OPO ~~must offer the kidney and pancreas in the following order:~~ **must**

1. ~~The host OPO m~~**Must** offer the kidney and pancreas according to classifications 1–~~54~~**54** in *Tables 11-45: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years Old and Less with a BMI less than or equal to 30 kg/m²* and *Table 11-56: Allocation of Kidneys and Pancreas from Donors more than 50 Years Old or with a BMI greater than 30 kg/m²*.
2. Then, the host OPO may do *either*:
 - a. Continue to offer the kidney and pancreas according to the remaining classifications in *Table 11-45* and *Table 11-56*.
 - b. Offer the pancreas to pancreas and islet candidates, but not kidney-pancreas candidates, according to the remaining classifications in *Table 11-45* and *Table 11-56* and offer the kidney to kidney candidates according to *Policy 8: Allocation of Kidneys*.

The host OPO may switch between options 2.a and 2.b above at any time after completing step 1 above.

11.4.B Pancreas Allocation When a Kidney is Unavailable

If a host OPO only has a pancreas, but not a kidney to offer for allocation, then the host OPO **must** offer the pancreas to pancreas and islet candidates but not kidney-pancreas candidates according to *Tables 11-45: Allocation of Kidneys and Pancreas from Deceased Donors 50 Years*

Old and Less with a BMI less than or equal to 30 kg/m² and Table 11-56: Allocation of Kidneys and Pancreas from Deceased Donors more than 50 Years Old or with a BMI Greater than 30 kg/m².

OPOs may not allocate a kidney to a potential pancreas recipient who is receiving the pancreas offer due to the match run prioritization of the potential recipient’s isolated pancreas registration.

11.4.C Organ Offer Limits

Any pancreas that will be ~~shared~~ allocated as ~~zero-antigen 0-ABDR~~ mismatches, either alone or in combination with kidneys, must be offered within eight hours after procurement.

If there are at least 10 ~~zero-antigen 0-ABDR~~ mismatched potential recipients on the match run, the pancreas must be offered to the first 10 ~~zero-antigen 0-ABDR~~ mismatched potential transplant recipients. If there are less than 10 ~~zero-antigen 0-ABDR~~ mismatched potential transplant recipients, the pancreas must be offered to all ~~zero-antigen 0-ABDR~~ mismatched potential transplant recipients.

If these offers are not accepted then the host OPO must:

- Allocate the ~~organ~~ kidney according to the match run under *Policy 8.5: Kidney Allocation Classifications and Rankings* and allocate the pancreas according to *Policy 11.4: Pancreas, Kidney-Pancreas, and Islet Allocation Classifications and Rankings*.
- Allocate the organ for the remaining ~~zero-antigen 0-ABDR~~ mismatched potential recipients.

11.4.D Blood Type for Kidney-Pancreas Allocation

Within each classification, kidney-pancreas will be allocated to candidates according to the blood type matching requirements in Table 11-34 below:

11-34: Allocation of Kidney-Pancreas by Blood Type

Kidney-Pancreas from Deceased Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O or blood type A, B, or AB if the candidate has a zero-antigen 0-ABDR mismatch with the deceased donor and a CPRA greater than or equal to 80 percent
Blood Type A	Blood type A or AB
Blood Type B	Blood type B
Blood Type AB	Blood type AB

11.4.E Sorting Within Each Classification

Within each allocation classification, pancreas, kidney-pancreas, and islet candidates are sorted in the following order: based on waiting time (longest to shortest).

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

11.4.F Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m²

Pancreas, kidney-pancreas, and islets from donors 50 years old or less and who have a BMI less than or equal to 30 kg/m² will be allocated to candidates according to *Table 11-45* based on waiting time.

Table 11-4: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m²

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
2	OPO's DSA	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
3	OPO's region	Zero antigen mismatch, CPRA greater than or equal to 80%, and are either pancreas or kidney-pancreas candidates
4	Nation	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
5	OPO's DSA	Pancreas or kidney-pancreas candidates
6	OPO's region	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates

Classification	Candidates that are within the:	And are:
7	OPO's region	Pancreas or kidney-pancreas candidates
8	Nation	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
9	Nation	Pancreas or kidney-pancreas candidates
10	OPO's DSA	Islet candidates
11	OPO's Region	Islet candidates
12	Nation	Islet candidates

Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors 50 Years Old and Less with a BMI Less Than or Equal To 30 kg/m²

Classification	Candidates that are	And registered at a transplant program that is at or within this distance from the donor hospital:
1	<u>Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%</u>	<u>250NM</u>
2	<u>Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%</u>	<u>250NM</u>
3	<u>Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%</u>	<u>Nation</u>
4	<u>Pancreas or kidney-pancreas candidates</u>	<u>250NM</u>
5	<u>Either pancreas or kidney-pancreas candidates, and CPRA greater than or equal to 80%</u>	<u>Nation</u>
6	<u>Pancreas or kidney-pancreas candidates</u>	<u>Nation</u>
7	<u>Islet candidates</u>	<u>250NM</u>
8	<u>Islet candidates</u>	<u>Nation</u>

11.4.G Deceased Donors More than 50 Years Old or with a BMI Greater Than 30 kg/m²

Pancreas, kidney-pancreas, and islets from deceased donors more than 50 years old or from deceased donors who have a BMI greater than 30 kg/m² are allocated to candidates according to *Table 11-56* based on waiting time below.

Table 11-5: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Old or with a BMI Greater Than 30 kg/m²

Classification	Candidates that are within the:	And are:
1	OPO's DSA	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
2	OPO's DSA	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
3	OPO's region	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
4	Nation	Zero antigen mismatch, CPRA greater than or equal to 80%, and either pancreas or kidney-pancreas candidates
5	OPO's DSA	Pancreas or kidney-pancreas candidates
6	OPO's DSA	Islet candidates
7	OPO's region	Islet candidates
8	Nation	Islet candidates
9	OPO's region	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
10	OPO's region	Pancreas or kidney-pancreas candidates
11	Nation	CPRA greater than or equal to 80% and either pancreas or kidney-pancreas candidates
12	Nation	Pancreas or kidney-pancreas candidates

**Table 11-6: Allocation of Kidney and Pancreas from Deceased Donors More Than 50 Years Old
or with a BMI Greater Than 30 kg/m²**

<u>Classification</u>	<u>Candidates that are:</u>	<u>And registered at a transplant program that is at or within this distance from the donor hospital:</u>
<u>1</u>	<u>Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%</u>	<u>250NM</u>
<u>2</u>	<u>Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%</u>	<u>250NM</u>
<u>3</u>	<u>Either pancreas or kidney-pancreas candidates, 0-ABDR mismatch, and CPRA greater than or equal to 80%</u>	<u>Nation</u>
<u>4</u>	<u>Pancreas or kidney-pancreas candidates</u>	<u>250NM</u>
<u>5</u>	<u>Islet candidates</u>	<u>250NM</u>
<u>6</u>	<u>Islet candidates</u>	<u>Nation</u>
<u>7</u>	<u>Either pancreas or kidney-pancreas candidates and CPRA greater than or equal to 80%</u>	<u>Nation</u>
<u>8</u>	<u>Pancreas or kidney-pancreas candidates</u>	<u>Nation</u>

11.5 Reallocation of Unsuitable Islets

Islets must be allocated to the most medically suitable candidate based on the transplant ~~hospital~~ program's Investigational New Drug (IND) application, as approved by the United States Food and Drug Administration (FDA). After islet processing is completed, the transplant ~~hospital~~ program must determine and document *both*:

1. Whether the islet preparation meets the transplant ~~hospital~~ program's islet product release criteria contained in the IND.
2. Whether the islets are medically suitable or medically unsuitable for the candidate that accepted the islets.

If the islets are found medically unsuitable for the candidate, the transplant ~~hospital~~ program must document the reason the islets were determined to be medically unsuitable for the candidate.

If the transplant ~~hospital~~ program determines that the islets are medically unsuitable for the candidate, the transplant ~~hospital~~ program will reallocate the islets according to *all* of the following criteria:

1. To a candidate that is medically suitable
2. To a candidate that is registered at a transplant ~~hospital~~ program covered by the same IND
3. The candidate's ~~waiting time (ranked longest to shortest)~~ allocation score according to *Table 11-1: Allocation Points*

The transplant ~~hospital~~ program that reallocates the islets must document that it followed this ~~P~~policy.

11.6 Facilitated Pancreas Allocation

11.6.A Transplant Program Qualifications

A transplant program qualifies to receive facilitated pancreas offers if within the two previous years it has transplanted a minimum of ~~five~~ two pancreas recovered from deceased donors located at hospitals more than 250 NM away from the transplant program. ~~recovered from deceased donors outside its DSA.~~ This includes pancreas transplanted as part of a multi-organ transplant.

11.6.B Facilitated Pancreas Offers

OPOs and the ~~Organ-Center~~ OPTN Contractor are permitted to make facilitated pancreas offers if no pancreas offer has been accepted three hours prior to the scheduled donor organ recovery. The OPO or ~~Organ-Center~~ OPTN Contractor must offer the pancreas only to potential transplant recipients registered at a transplant program that participates in facilitated pancreas allocation. Facilitated pancreas offers must be made in the order of the match run, and OPOs will only have access to facilitated allocation after all ~~local~~ pancreas and kidney-pancreas offers made to candidates registered at transplant programs within 250 nautical miles of the donor hospital have been declined.

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