

**3.8 PANCREAS ALLOCATION.** The following policies shall apply to the allocation of pancreata.

**3.8.1 Pancreas Organ Allocation.** For local pancreas allocation, recipients may be selected from candidates awaiting an isolated pancreas, kidney-pancreas combination, or a combined solid organ-islet transplant from the same donor, unless there is a candidate on the Waiting List who meets the requirements of Policy 3.5.4 or Policy 3.8.1.7 and for whom there is a zero antigen mismatch with the donor. Within the Waiting List for isolated pancreas, candidates shall be prioritized as set forth in Policy 3.8.1.1 below. Within the Waiting Lists for kidney-pancreas combination and combined solid organ-islet transplant, length of time waiting shall be considered for the selection of organ recipients. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive. For combined kidney-pancreas candidates, blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.1, unless there is a zero antigen mismatch between the candidate and donor and the candidate is highly sensitized as defined in Policy 3.5.4. If the pancreas is not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch candidate or pursuant to Policy 3.5.4 the pancreas, if procured from a donor less than or equal to 50 years old and with body mass index (BMI) less than or equal to 30 kg/m<sup>2</sup>, shall be allocated regionally and then nationally, or for candidates listed for facilitated pancreas placement as described in Policy 3.8.1.3, in the following sequence. Pancreata procured from donors greater than 50 years old or with body mass index (BMI) greater than 30 kg/m<sup>2</sup> that are not placed locally for an isolated or combined whole organ transplant, a combined solid organ-islet transplant, a zero antigen mismatch candidate or pursuant to Policy 3.5.4, shall be allocated according to Policy 3.8.1.5 below:

**3.8.1.1 Local Whole Pancreas Allocation.** Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield an 80% or greater probability of incompatibility with deceased donors (i.e., Calculated Panel Reactive Antibody (CPRA)  $\geq$  80%)<sup>1</sup>; and
- All other isolated pancreas candidates.

**3.8.1.2 Regional Whole Pancreas Allocation.** Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%)<sup>1</sup>;
- All other isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.

**3.8.1.3 National Whole Pancreas Allocation.** Within each of the following categories, allocation shall be based on the transplant candidate's length of time waiting. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

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<sup>1</sup> For purposes of Policy 3.8, requirements for identifying and listing unacceptable antigens, as well as the definition of and parameters for calculating CPRA, are the same as those listed in Policy 3.5.11.3 (Sensitized Wait List Candidates) for assigning priority in the allocation of deceased donor kidneys.

- **Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%)<sup>1</sup>;**
- All other isolated pancreas candidates; and
- Combined kidney-pancreas candidates if the kidney is available. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.

**3.8.1.4 Facilitated Pancreas Allocation.** In the event that the Organ Center has attempted, but has been unable, to place the pancreas for a period of at least five (5) hours, or upon notice to the Organ Center that organ retrieval is anticipated within one (1) hour, then irrespective of whether the entire regional and/or national Waiting List of candidates has by that time been exhausted, the pancreas shall be offered through the Organ Center for candidates listed with those transplant centers that have recorded in writing their desire, to participate in the system of facilitated pancreas allocation. A pancreas offered by this facilitated method shall be offered to candidates who have not previously received an offer for that pancreas. The pancreas shall be offered, in the following sequence, based on the transplant candidate's length of waiting time within each of the enumerated categories below. Candidates shall continue to accrue waiting time while registered on the Waiting List as inactive.

- Isolated pancreas candidates with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%)<sup>1</sup>; and
- Combined kidney-pancreas candidates if the kidney is voluntarily being offered. Blood type O kidneys must be transplanted into blood type O recipients as specified in Policy 3.5.2 and the kidney must be paid back as specified in Policy 3.5.5.

Any transplant center desiring to participate in this system shall be allowed to do so provided that it (a) agrees to accept offers for pancreata that have been procured by institutions located outside of its OPO (b) agrees to accept offers for pancreata on a conditional basis pending tissue typing information and redistribution of the organs pursuant to Policy 3.8.1.7 in the event there is a candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, and (c) documents this agreement and its desire to participate in the system in writing.

**3.8.1.5 Islet Transplantation.** If the donor is less than or equal to 50 years old and has body mass index (BMI) less than or equal to 30 kg/m<sup>2</sup> and suitable recipient is not identified by the allocation criteria specified in Policies 3.8.1, 3.8.1.1, 3.8.1.2, 3.8.1.3, or 3.8.1.4, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

If the donor is greater than 50 years old or has BMI greater than 30 kg/m<sup>2</sup>, and a suitable recipient is not identified at the local level of organ allocation by the criteria specified in Policy 3.8.1, then the Host OPO shall offer the pancreas locally for clinical islet transplantation. If the organ is not used locally, the Host OPO shall offer the pancreas regionally and then nationally for clinical islet transplantation, and then regionally followed by nationally for whole organ transplantation. If the organ is not used for transplantation, then the Host OPO should offer the pancreas for research.

**3.8.1.6 Islet Allocation Protocol.** Allocation of pancreata for islet transplantation shall be to the most medically suitable candidate based upon need and transplant candidate length of waiting time. After islet processing is completed, the transplant center will determine if the islet preparation is medically suitable for

the candidate. Medical suitability is defined as meeting the islet transplant center's islet product release criteria contained in the center's Investigational New Drug (IND) application, as approved by the FDA. The center must document whether the islets are medically suitable or medically unsuitable for the candidate for whom the center accepted the islets. If the islets are medically unsuitable for the candidate, the center must also document the reason the islets were medically unsuitable for the candidate. This documentation must be maintained and submitted upon request.

If the transplant center determines that the islets are medically unsuitable for the candidate for whom the center accepted the islets, the islets from that pancreas will be reallocated to a medically suitable candidate at a transplant center covered by the same IND, based upon waiting time. The transplant center that accepted the islets on behalf of the original candidate is responsible for documenting:

- to which candidate the center re-allocated the islets, and
- that the center re-allocated the islets to the medically suitable candidate covered by the same IND who had the most waiting time.

The transplant center must maintain this documentation and submit it upon request.

Islet allocation must abide by all applicable OPTN/UNOS policies, including but not limited to:

- Policy 3.2.1 (Mandatory Listing of Potential Recipients), which states that all candidates who are potential recipients of deceased donor organs must be on the Waiting List,
- Policy 3.2.1.4 (Prohibition for Organ Offers to Non-Members), which stipulates that organ offers cannot be made to non-member centers,
- Policy 3.2.4 (Match System Access), which requires that organs only be allocated to candidates who appear on a match run,
- Policy 6.4.1 (Exportation), which states that the exportation of organs from the United States or its territories is prohibited unless a well documented and verifiable effort, coordinated through the Organ Center, has failed to find a suitable recipient for that organ on the Waiting List.

### **Waiting Time**

A candidate is eligible to accrue waiting time:

- while listed in an active or inactive status; and
- until the candidate has received a maximum of three islet infusions.

Waiting time will begin when a candidate is placed on Waiting List. Waiting time will end when the candidate is removed from the waiting list. Waiting time will accrue for a candidate until he/she has received a maximum of three islet infusions or the transplant center removes the candidate from the waiting list, whichever is the first to occur. If the candidate is still listed at this time or subsequently added back to the Waiting List, waiting time will start anew.

One point will be assigned to the candidate waiting for the longest period with fractions of points assigned proportionately to all other candidates, according to their relative waiting time. For example, if there are 75 candidates waiting for islets, the candidate waiting the longest would receive 1 point ( $75/75 \times 1 = 1$ ). A person with the 60th longest time of waiting would be assigned 0.2 points ( $(75-60)/75 \times 1 = 0.2$ ). The calculation of points is conducted separately for each geographic (local, regional and national) level of islet allocation. The local points calculation includes only candidates on the local Waiting List. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on

the national list excluding all candidates listed on the Host OPO's local or regional waiting list.

#### **Active and Inactive Status**

A candidate is **not** eligible for active status if the candidate:

- Is insulin independent **and**
- Has an HbA1c value of less than or equal to 6.5%.

The transplant center is responsible for keeping the candidate's listing status current in UNet<sup>SM</sup>.

If the candidate is listed as active and is insulin dependent, the transplant center must maintain documentation in the candidate's record of his/her current insulin status. To retain active status for an insulin dependent candidate, the transplant center must document in the candidate's record every six months that the candidate is currently insulin dependent.

If the candidate is listed as active and is insulin independent, the transplant center must maintain documentation in the candidate's record of his/her insulin status and HbA1c level with the date of the HbA1c test. To retain active status for an insulin independent candidate, the transplant center must document in the candidate's record every six months:

- That the candidate has had an HbA1c test within the past six months with a result of greater than 6.5%, **and**
- That the candidate is insulin independent.

The transplant center must use the most recent HbA1c value when determining whether the candidate is eligible for active status.

If a candidate's clinical condition changes, and the candidate is no longer eligible for active status, the transplant center must change the candidate's status in UNet<sup>SM</sup> within 72 hours of the transplant center's knowledge of this candidate's clinical change. The transplant center must maintain documentation in the candidate's record of when the center learned of this clinical change. If a transplant center wishes to list an inactive candidate as active, the transplant center must have documentation that the candidate had the appropriate HbA1c level and insulin status in the past six months. The transplant center must present any documentation required by this policy to the OPTN upon request.

#### **Removal from the Waiting List**

The transplant center must remove the candidate from the waiting list within 24 hours of the candidate receiving his/her third islet infusion.

- 3.8.1.7 Mandatory Sharing of Zero Antigen Mismatch Pancreata.** In the event there is a candidate on the Waiting List for whom there is a zero antigen mismatch with the donor, the pancreas from that donor shall be offered, first, to the appropriate Member for any highly sensitized candidate waiting for a combined kidney/pancreas transplant with a zero antigen mismatch, pursuant to Policy 3.5.4 (first locally, then regionally, and then nationally, based upon length of time waiting). The pancreas shall then be offered to the appropriate Member for any highly sensitized candidate (i.e. candidate with, unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80%)<sup>1</sup>) waiting for an isolated pancreas transplant with a zero antigen mismatch, first locally, then regionally, and then nationally, based upon length of time waiting, unless there is a candidate listed on the Host OPO's local candidate waiting list for combined kidney/pancreas or isolated pancreas transplantation who is mismatched with the donor and also has unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to

yield CPRA  $\geq$  80%. In this event, for local allocation, the pancreas shall be offered for the mismatched candidate(s) with unacceptable HLA antigens listed in UNet<sup>SM</sup> sufficient to yield CPRA  $\geq$  80% (based upon length of time waiting if more than one candidate meets these criteria) before being offered for highly sensitized zero antigen mismatched isolated pancreas transplant candidates regionally and nationally.

#### **3.8.1.7.1**

**Organ Offer Limit.** All pancreata to be shared as zero antigen mismatches, either alone or in combination with kidneys, must be offered to the appropriate recipient transplant centers through UNet<sup>SM</sup> or through the Organ Center within eight hours after organ procurement. Offers must be made for the first 10 zero antigen mismatched potential recipients<sup>2</sup> according to the national lists of candidates waiting for combined kidney/pancreas or isolated pancreas transplantation, as applicable. If there are less than 10 zero antigen mismatched potential recipients on the match list, offers must be made for all zero antigen mismatched potential recipients on the match list. If these offers are turned down (either explicitly refused or the notification time or evaluation time is exceeded as defined in Policy 3.4.1), the Host OPO must either:

- allocate the organ(s) according to the standard geographic sequence of kidney allocation under Policy 3.5.6 and pancreas allocation under Policy 3.8.1, as applicable (first locally, then regionally, and then nationally); or
- allocate the organ(s) for the remaining zero antigen mismatched potential recipients.

If the Host OPO continues to offer kidney/pancreas combinations for zero antigen mismatched potential recipients beyond the 10<sup>th</sup> potential recipient, a kidney payback will be generated pursuant to Policy 3.5.5 (Payback Requirements). If the Host OPO chooses to share a zero antigen mismatched kidney/pancreas combination through UNet<sup>SM</sup>, the Host OPO must submit a completed Kidney Payback Accounting Sheet within 5 business days of the recovery of the organ(s), defined as cross clamp of the donor aorta, to report the share. A payback credit will not be assigned until: 1) the Organ Center receives the Kidney Payback Accounting Sheet documenting the zero antigen mismatch share; and 2) the zero antigen mismatch share can be verified (i.e. cross clamp and final acceptance has been entered) in UNet<sup>SM</sup>. No obligation to payback the pancreas will be generated. If the Host OPO does not report the sharing within 5 business days of the organ(s) recovery, the OPO will forfeit the payback credit.

**3.8.2 Waiting Time Adjustment.** Waiting time accrued by a transplant candidate for one or more organs shall be transferred as follows if it is determined that the candidate requires another organ or organ combination:

- (i) Waiting time accrued by a kidney transplant candidate while registered on the Waiting List shall be assigned also to the listing for a combined kidney-pancreas transplant if it is determined that the candidate requires a combined kidney-pancreas transplant.
- (ii) Waiting time accrued by a kidney transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the candidate requires a pancreas transplant.
- (iii) Waiting time accrued by a kidney-pancreas transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated pancreas transplant if it is determined that the candidate is suitable for a pancreas alone transplant.

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<sup>2</sup> For the purposes of Policy 3.8.1.7.1, zero antigen mismatched potential recipients are zero antigen mismatched potential recipients who appear in the zero antigen mismatch classification on the match run.

- (iv) Waiting time accrued by a kidney-pancreas transplant candidate while registered on the Waiting List shall be assigned also to the listing for an isolated kidney transplant if it is determined that the candidate is suitable for a kidney alone transplant.
- (v) Waiting time accrued by an isolated pancreas transplant candidate while registered on the Waiting List shall not be assigned to the listing for a combined kidney-pancreas transplant.
- (vi) Waiting time accrued by an isolated pancreas transplant candidate while registered on the Waiting List shall not be assigned to the listing for an isolated kidney transplant.

**3.8.2.1 Waiting Time Transfer for Whole Pancreas and Pancreatic Islet Cell Candidates**

- (i) Waiting time accrued by an isolated whole pancreas transplant candidate while registered on the waiting list shall be transferred to the listing for pancreatic islet cell transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the whole pancreas and pancreatic islet waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.
- (ii) Waiting time accrued by a pancreatic islet cell transplant candidate while registered on the waiting list shall be transferred to the listing for whole pancreas transplant after consideration and approval of a request for such transfer by the OPTN/UNOS Pancreas Transplantation Committee. Waiting time transfer requests must document to the satisfaction of the Pancreas Transplantation Committee that such transfer is reasonable and is in the candidate's best interest, and comply with other application requirements as may be developed by the Committee from time to time. Requests for waiting time transfer between the pancreatic islet and whole pancreas waiting lists, along with decisions of the Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.

**3.8.3 Inclusion of HLA Data.** Recipient HLA information must be included when listing a potential pancreas or combined kidney-pancreas candidate on the Waiting List.

**3.8.4 Reporting Candidates' Unacceptable Antigens.** To receive priority in the allocation of isolated pancreata based upon CPRA, candidate unacceptable antigens sufficient to yield CPRA  $\geq$  80%) must be entered into UNet<sup>SM</sup> as described in Policies 3.8.1.1 – 3.8.1.4. Pancreata from donors with antigens included among the unacceptable antigens for a candidate will not be offered for that candidate.

**3.8.5 Regional or National Allocation to Alternate Recipients.** For a pancreas that is shared regionally or nationally, the Organ Center will advise the OPO for the transplant center for the candidate who has the highest number of points at that center to seek alternate candidates on the OPO's waiting list to receive the pancreas in the event that the pancreas cannot be used by that candidate. Selection of alternate candidates must be according to the pancreas allocation policy.

### **3.8.6 Minimum Information for Pancreas Offers.**

**3.8.6.1 Essential Information Category.** The Host OPO or donor center must provide the following donor information, with the exception of pending serologies, to the recipient center with each pancreas offer:

- (i) Donor name and Donor I.D. number, age, sex, race and weight;
- (ii) Date of admission for the current hospitalization;
- (iii) Diagnosis;
- (iv) Blood type;
- (v) Current history of abdominal injuries and operations including pancreatic trauma;
- (vi) Pertinent past medical or social history including pancreatitis;
- (vii) Current history of average blood pressure, hypotensive episodes, cardiac arrest, average urine output, and oliguria;
- (viii) Indications of sepsis;
- (ix) Pre-or post-transfusion serologies as indicated in 2.2.7.1 (pre-transfusion preferred);
- (x) Current medication and transfusion history;
- (xi) Blood glucose;
- (xii) Amylase;
- (xiii) Insulin protocol;
- (xiv) Alcohol use (if known);
- (xv) Familial history of diabetes; and
- (xvi) HLAA, B, Bw4, Bw6, and DR antigens.

### **3.8.7 Removal of Pancreas Transplant Candidates from Pancreas Waiting Lists When Transplanted or Deceased.**

If a pancreas transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all pancreas waiting lists and shall notify within 24 hours of the event. If the pancreas recipient is again added to a pancreas waiting list, waiting time shall begin as of the date and time the candidate is relisted. If the recipient is waiting for a combined kidney-pancreas transplant and receives only an isolated pancreas transplant, the recipient's accrued waiting time while listed for the combined organ transplant shall automatically be transferred to the isolated Kidney Waiting List.

### **3.8.8 Waiting Time Reinstatement for Pancreas Recipients.**

In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor pancreas, the candidate may be reinstated to the waiting list and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as pancreas graft failure requiring the removal of the organ within the first two weeks of transplant. Waiting time will be reinstated upon receipt by the Organ Center

- A completed Pancreas Waiting Time Reinstatement Form, and
  - A pancreatectomy operative report
- OR
- A completed Pancreas Waiting Time Reinstatement Form, and
  - A statement of intent from the transplant center to perform a pancreatectomy, and
  - A statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed. This documentation must be maintained and submitted upon request.

The Organ Center will send a notice of waiting time reinstatement to the transplant center involved.

**3.8.9 Prospective Crossmatching.** A prospective crossmatch is mandatory for all candidates, except where clinical circumstances support its omission. The transplant program and its histocompatibility laboratory must have a joint written policy that states when the prospective crossmatch may be omitted. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D to Policy 3.