

Definition of Pancreas Graft Failure

Sponsoring Committee:	Pancreas Transplantation
Policy/Bylaws Affected:	Policies 1.2 <i>Definitions</i>, 3.6 <i>Waiting Time</i>
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Problem Statement

Currently, there is no specific definition for pancreas graft failure in OPTN Policy. Consequently, transplant programs report graft failure at varying degrees. This variability limits the OPTN’s ability to analyze and compare pancreas programs’ outcomes. This proposal establishes a definition within policy that will help transplant professionals identify when pancreas allograft failure has occurred, and explain how these professionals should document pancreas graft failure events.

Summary of Changes

We’ll establish policy for when a pancreas graft has failed (modifications to Policy 1.2: *Definitions*), which will streamline TIEDI help documentation about how professionals should document pancreas graft failure, and we’ll update the graft status section in the OPTN Pancreas and Kidney Pancreas Transplant Recipient Registration and Transplant Recipient Follow-Up Forms (“OPTN pancreas forms”).

What Members Need to Do

Transplant hospitals should become familiar with the new policy definition for pancreas graft failure, be aware of the changes to the pancreas data collection forms, and understand how the two changes interact. You also need to understand what constitutes a pancreas graft failure, and know how to fill out the graft status section of the pancreas OPTN data collection forms. You will be expected to accurately report graft failure based upon the proposed language.

You should also be aware of additional fields in the pancreas data collection forms. You will be required to complete these additional fields when filling out your forms.

Affected Policy/Bylaw Language:

New language is underlined and language that will be deleted is ~~struck through~~

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

Graft failure

For all organs except pancreas, graft failure ~~o~~occurs when any of the following occurs:

- ~~a~~ A recipient’s transplanted organ is removed,
- ~~a~~ A recipient dies,
- ~~or a~~ A recipient is placed on a chronic allograft support system-

Pancreas graft failure occurs when any of the following occurs:

- A recipient’s transplanted pancreas is removed

- A recipient re-registers for a pancreas
- A recipient registers for an islet transplant after receiving a pancreas transplant
- A recipient's total insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- A recipient dies

3.6.B.ii Non-function of a Transplanted Pancreas

Immediate and permanent non-function of a transplanted pancreas is defined as ~~pancreas graft failure requiring the~~ removal of the transplanted pancreas within ~~the~~ first 14 days of after transplant.

Pancreas waiting time will be reinstated when the OPTN Contractor receives a completed *Pancreas Waiting Time Reinstatement Form* and *either* of the following:

- An operative report of the removal of the pancreas.
- A statement of intent from the transplant hospital to remove the transplanted pancreas, and a statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed.

The transplant hospital must maintain this documentation. The OPTN Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.