OPTN

Public Comment Proposal

Programming VCA Allocation in UNet

OPTN Vascular Composite Allograft Committee

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Contents

Programming VCA Allocation in UNet

Affected Policies:	*2.2: OPO Responsibilities* *3.6: Waiting Time* *5.3.B: Infectious Disease Screening Criteria* *5.4.B: Order of Allocation* *5.6.A: Receiving and Reviewing Organ Offers* *5.6.B: Time Limit for Review and Acceptance of Organ Offers* *12.2: VCA Allocation* *18.1.B: Timely Submission of Certain Data* *18.3 Recording and Reporting the Outcomes of Organ Offers*
Sponsoring Committee:	*Vascular Composite Allograft*
Public Comment Period:	*August 4, 2020 – October 1, 2020*

Executive Summary

The purpose of this proposal is to update policy language to enable programming Vascular Composite Allograft (VCA) allocation and data collection in UNet℠, including DonorNet® and Waitlist℠. When OPTN oversight of VCAs began in 2014, the Board of Directors (BOD) elected to exclude VCA from UNet due to the novelty of the field and programming time constraints.[1] As a result of this exclusion, the allocation and data collection for VCAs are conducted as using a separate and manual process. As the VCA field has grown, especially for uterus procedures, the Committee recommends programming VCA allocation and data collection in UNet.[2] Policy language removals and policy additions will be required to integrate VCA in UNet.

The programming of VCA in UNet will enable all VCA recipients to be identified and rank ordered by the OPTN computer match program and will allow communication of that matching to occur directly in the system. This programming will promote a more unified system for identifying VCA recipients and will align with matching processes currently used for all other major organs. While the OPTN has maintained separate system to match VCA donors with potential VCA transplant recipients, programming VCA in UNet will result in one consistent automated system for management of OPTN records and the transplant candidate waiting list. Following programming and implementation, transplant hospitals, Organ Procurement Organizations (OPO), and histocompatibility labs that carry out VCA procedures will be required to use UNet.

[1] Report to the Board of Directors, OPTN Vascular Composite Allograft Committee, June 2014, https://optn.transplant.hrsa.gov/media/1335/vca_boardreport_20140616.pdf (accessed May 22, 2020)
[2] May 13, 2020, Vascular Composite Allograft Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

Background

On July 3, 2014 the Department of Health and Human Services (HHS) added VCAs to the definition of organs covered by the OPTN Final Rule.[3] The expansion of this definition requires the OPTN to match VCA donor organs to potential recipients and develop VCA policies consistent with the OPTN Final Rule. The addition of VCAs to the OPTN's purview also requires hospitals wishing to perform VCA procedures to become OPTN members and comply with the OPTN Final Rule, policies, and data submission requirements.[4]

UNet is an electronic network comprised of multiple systems, designed to link transplant hospitals, OPOs, and histocompatibility labs on one platform.[5] This secure data sharing platform allows transplant professionals to list patients for transplant, match candidates with potential donors, and submit OPTN required data. UNet applications include DonorNet, Waitlist, and TIEDI®.[6] This network promotes standardized and efficient organ offer and acceptance procedures.

When OPTN VCA oversight began, the Board of Directors elected not to program VCA in UNet.[7] There were relatively few VCA transplants in 2014. The Board was also uncertain about the future of VCA and did not anticipate the rapid evolution this field has seen in the past four years. VCA was specifically excluded from OPTN policies that would require reporting in UNet. The Committee agreed to circle back to programming VCA in UNet for consideration at a later date.

In lieu of the OPTN computer matching system and UNet, a separate manual VCA matching process is administered.[8] The current system requires transplant programs to register VCA candidates by manually filling out a form and sending it to the OPTN. The OPTN compiles these candidate registration forms and distributes them to OPOs. OPOs match VCA donors to candidates using this list. Should a VCA donor be suitable for more than one candidate, the organ is offered to candidates within 500 nautical miles first. If the VCA is not accepted by a candidate within 500 nautical miles, the organ is offered nationally. Waiting time is used as the tie breaker between candidates within each classification.[9]

In 2016, the number of uterus transplants started to grow with donations from both deceased and living donors. To date, there have been 12 deceased uterus donors and 19 living uterus donors.[10] These numbers are expected to continue to rise with the availability and popularity of the procedure. As VCA allocation volume continues to increase, particularly for uterus transplantation, the Committee considers that programming VCA in UNet will allow greater access and efficiency for VCA transplant

3 Federal Register, Department of Health and Human Services, July 2013, https://www.federalregister.gov/documents/2013/07/03/2013-15731/organ-procurement-and-transplantation-network (accessed May 27, 2020)
4 Federal Register, Department of Health and Human Services, July 2013, https://www.federalregister.gov/documents/2013/07/03/2013-15731/organ-procurement-and-transplantation-network (accessed May 27, 2020)
5 UNet, United Network for Organ Sharing, 2020, https://unos.org/technology/unet/ (accessed May 27, 2020)
6 Id.
7 Report to the Board of Directors, OPTN Vascular Composite Allograft Committee, June 2014, https://optn.transplant.hrsa.gov/media/1335/vca_boardreport_20140616.pdf (accessed May 22, 2020)
8 Id.
9 OPTN Policy 12.2 VCA Allocation. Available at https://optn.transplant.hrsa.gov/
10OPTN Data as of 06/24/20

programs to consider VCA offers, and provide a platform that will better integrate with upcoming and concurrent data collection projects.

VCA programming in UNet will enable the OPTN to streamline VCA TIEDI submission procedures, enabling electronic submission of recent and future changes to VCA data collection. Significant changes to VCA data collection were recently passed by the OPTN Board.[11] These changes will impact data collection for deceased donor VCAs of all types including head and neck, upper limb, and uterus transplant recipients. Programming the recently approved requirements in the current system would be inefficient and miss an opportunity to integrate VCA with other organs. Additionally, another VCA Committee sponsored public comment proposal, *Modify Data Collection on VCA Living Donors*, would require data collection specific to living VCA donors on the Living Donor Registration (LDR) and Living Donor Follow- up (LDF) data collection instruments.[12] This highlights the need for this proposal which will address inefficiencies in the current system for deceased donor VCA processes. Programming in UNet will make all VCA data collection instruments accessible through UNet, as they are for the other organs. This will also provide a centralized and more efficient access point for members to consider VCA organ offers and report required data.

As the number of uterus transplants have grown over the past four years and a major revision to VCA data collection for the Transplant Recipient Registration (TRR) and Transplant Recipient Follow Up (TRF) was approved by the OPTN Board of Directors (BOD) in June 2020, so has the impetus to program VCA in UNet.

Purpose

The purpose of this proposal is to update policy language to enable the programming of VCA allocation in UNet, including DonorNet and Waitlist. VCA allocation is currently managed outside of UNet, requiring OPO members to use a separate manual VCA matching process.[13] The current VCA matching process is inconsistent with the allocation and data collection data system used for other organs. This inhibits operational and programming efficiencies as well as data integration with the organ types.

Overview of Proposal

This proposal will update policy language to enable programming of VCA allocation in UNet, including DonorNet and Waitlist.

Policy Removals

These proposed policy changes will remove language that excludes VCA from programming in UNet. Policy sections with current VCA exclusions and the areas where the VCA exclusion would be removed are displayed in **Table 1** below.

11 June 8, 2020, OPTN Board of Directors Meeting Summary. Available at https://optn.transplant.hrsa.gov/(accessed May 27, 2020)
12 Modify Data Collection on VCA Living Donors, OPTN Vascular Composite Allograft Committee, August 2020 Available at https://optn.transplant.hrsa.gov/
13 Report to the Board of Directors, OPTN Vascular Composite Allograft Committee, June 2014, https://optn.transplant.hrsa.gov/media/1335/vca_boardreport_20140616.pdf (accessed May 22, 2020)

Table 1: OPTN Policy Language with Current VCA Exclusion Proposed for Removal

Policy Section	Current VCA Exclusion to be Removed
2.2 OPO Responsibilities	OPO requirement for executing the match run and using the resulting match for each deceased donor organ allocation
5.4.B Order of Allocation	Requirements for using the match run and released organs
5.6.A Receiving and Reviewing Organ Offers	Transplant hospital requirement to view organ offers and respond to these offers through the match system
5.6.B Time Limit for Review and Acceptance of Organ Offers	Transplant hospital requirement to respond to initial (primary) Potential Transplant Recipient (PTR) offer within one hour and provisional yes within 30 minutes
12.2 VCA Allocation	Separate OPO documentation requirements
18.1.B Timely Submission of Certain Data	Stand-alone VCA donor and candidate reporting data collection instruments (VCA Candidate List and Candidate Removal Worksheet)
18.3 Recording and Reporting the Outcomes of Organ Offers	Requirement for OPOs to report refusal codes on PTR within 30 days and transplant hospitals to confirm or amend within 45 days

Policy Additions

These proposed policy updates will add language that is necessary to align and have VCA function within UNet. The language proposed for addition to OPTN policy are displayed in **Table 2** below.

Table 2: New OPTN Policy Language

Policy Section	New Policy to Align with UNet Programming
3.6.A Waiting Time for Inactive Candidates	• Any VCA candidate will accrue unlimited waiting time while inactive
5.3.B Infectious Disease Screening Criteria	• Adds ability for transplant programs to select for candidates to be screened off matches for Hepatitis B core antibody and NAT as well as Hepatitis C antibody and NAT. This policy and functionality currently exists for other organs. • Adds VCA to HOPE Act screening language. This policy and functionality currently exists for other organs.
18.1.B Timely Submission of Certain Data	• Adds VCA to required reporting for the UNet recipient histocompatibility (RHS) data collection instrument • Adds requirement to complete the Potential Transplant Recipient (PTR) for VCA • Adds requirement for completing Waiting List Removal for VCA • Adds requirement for completing Transplant Candidate Registration (TCR) for VCA

NOTA and Final Rule Analysis

NOTA requires the OPTN to establish a national transplant candidate waiting list in addition to "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs".[14] The OPTN Final Rule defines the "OPTN computer match program" as "a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s)."[15]

Potential transplant recipients must be ranked by the OPTN computer match program by the organ specific allocation criteria. If a donor organ does not meet a transplant program's criteria, transplant candidates of that program will not appear on the ranked list of potential recipients for that organ.[16] The programming of VCA in UNet will allow all VCA recipients to be identified and rank ordered by the OPTN computer match program, as opposed to the current manual VCA matching process that is separate and does not use the OPTN computer match program. The programming of VCA in UNet will promote a more organized system for identifying VCA recipients and will align with matching process currently used for all other major organs.

The Final Rule also requires that the OPTN maintain records and operate an automated system for managing information on transplant candidates, transplant recipients, and organ donors.[17] The OPTN must maintain a computerized list of individuals waiting for transplant.[18] While the OPTN has maintained separate computerized system to match VCA donors with potential VCA transplant recipients, programming VCA in UNet will result in one consistent system for management of OPTN records and the transplant candidate waiting list.

Authority

NOTA requires the OPTN to establish a national transplant candidate waiting list in addition to "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs".[19] OPTN *Policy 1.1.C: Reporting of Information to the OPTN Contractor* requires members to report requested information to ensure compliance with OPTN policies and gives the OPTN the authority to determine the method and format for required reporting.[20]

Implementation Considerations

Member Operations

Transplant hospitals, OPOs, and histocompatibility labs will be required to use UNet instead of the separate manual VCA matching system. OPOs will be required to enter VCA donor data, complete match

[14] National Organ Transplant Act (NOTA), as amended, 42 USC §274(b)(2)(A).
[15] 42 CFR §121.2
[16] Id.
[17] 42 CFR §121.11(a)
[18] 42 CFR §121.11(a)(1)(i)
[19] National Organ Transplant Act (NOTA), as amended, 42 USC §274(b)(2)(A).
[20] OPTN Policies Effective as of June 18, 2020. Available at https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.

runs, make electronic organ offers, and provide supplemental medical donor information through the DonorNet application in UNet. Transplant hospitals will be required to view posted VCA donor information and accept or refuse organs through the Waitlist application in UNet. OPTN members will also submit required VCA candidate and living donor registration and follow-up data through the TIEDI application on UNet.

OPTN Operations

This proposal will require programming changes. The OPTN will be responsible for notifying members of new VCA UNet requirements. OPTN will follow established protocols to inform members of any policy changes through Policy Notices. The OPTN will also provide educational materials to support members' usage of UNet throughout the VCA donation and transplantation process.

Potential Impact on Select Patient Populations

This proposal will impact all VCA candidates and recipients. Programming VCA allocation in UNet will allow for more efficient matching with use of the OPTN computer system. More efficient organ matching could promote an increase of transplanted VCAs and a decrease in organ wastage. To date, there have been 12 deceased uterus donors and 19 living uterus donors. 17 upper limb bilateral and 18 unilateral procedures have also been completed as well as 18 head and neck VCA procedures.[21] Data reporting from donors and recipients will be necessary to monitor patient safety and outcomes. Programming VCA in UNet will promote more organized data collection and management.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on Organ Procurement Organizations

There is minimal expected fiscal impact to OPOs.

VCA allocation is currently managed outside of UNet by the UNOS Organ Center, requiring OPO members to use a separate application. If VCA volume increases, particularly for uterus transplants, programming VCA allocation in UNet will allow for greater access and efficiency for VCA transplant programs to consider VCA offers. This standardization with how other organs are allocated also provides a platform for VCA to integrate with future or concurrent data collection projects. The proposal does not include data collection.

OPOs may be required to work with their medical record vendor to make any needed updates. OPO reporting systems may also require updates. All work would now be completed in UNet which would likely be more efficient than using separate systems for VCA and other deceased donors, as is done currently. Staff education on different types of VCA programs, including VCA authorization, evaluation and recovery may also be needed. These items may be a cost to OPOs.

[21] OPTN Data as of 6/24/20

Projected Impact on Transplant Hospitals

The only anticipated fiscal impact to transplant hospitals is associated with time and resources required for training staff in UNet. However, most staff that would require training currently use UNet when managing allocation for other organ types. Moving all allocation processes to a single system will reduce the need to train employees in multiple systems.

Projected Impact on the OPTN

This is an enterprise sized project. It is estimated that it will take approximately 8,800 hours to implement this proposal.

Post-implementation Monitoring

Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The OPTN will report the number of VCA candidate additions and removals, VCA living donors, and VCA transplants entered in UNet three months after implementation.

Conclusion

This proposal aims to update policy language to allow the programming of VCA in UNet. The presented policy additions and removals will allow for VCA organ matching and management processes to be carried out in UNet. While the OPTN has maintained records for VCA through a separate system, programming VCA in UNet will result in one comprehensive system for the management of OPTN records and the transplant candidate waiting list. Upon implementation, transplant hospitals, OPOs, and Histocompatibility labs will be required to utilize UNet for VCA processes and procedures. The programming of VCA in UNet will promote more efficient organ placement and data reporting on one consistent system.

Policy and/or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

2.2 OPO Responsibilities

The host OPO is also responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the clinical management of the deceased donor.
8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. ~~11.~~ Executing the match run and using the resulting match for each deceased donor organ allocation. ~~The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.~~
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN Contractor upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN Contractor upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

3.6 Waiting Time

3.6.A Waiting Time for Inactive Candidates

Candidates accrue waiting time while inactive according to *Table 3-3* below. Inactive candidates do not receive organ offers.

Table 3-3: Waiting Time for Inactive Candidates

If the candidate is registered for the following organ…	Then the candidate accrues waiting time while inactive as follows…
Heart	No time
Intestine	Up to 30 cumulative days
Kidney	Unlimited time
Kidney-pancreas	Unlimited time
Liver	No time
Lung and is at least 12 years old	No time
Lung and is less than 12 years old	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
Any VCA	Unlimited time
All other organs	Up to 30 days

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below:

Table 5-1: Donor Infectious Disease Screening Options

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, any VCA
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, any VCA
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, any VCA
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, any VCA

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Human Immunodeficiency Virus (HIV); Organs from HIV-positive donors may only be recovered and transplanted according to the requirements in the Final Rule.	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, any VCA

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the PTRs appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates' data with the OPTN Contractor. The host OPO must re-execute the match run to allocate the organ.
5. Extra vessels allocated with an organ but not required for its transplant can be shared according to *Policy 16.6.A: Extra Vessels Use and Sharing*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all PTRs on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

~~This policy does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.~~

5.6.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system. ~~The previous sentence does not apply to VCA transplants.~~

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.

5.6.B Time Limit for Review and Acceptance of Organ Offers

This policy does not apply to expedited liver offers as outlined in *Policy 9.10.B: Expedited Liver Offers.*

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to *Policy 2.11: Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

The transplant hospital must respond as required by these timeframes or it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

~~This policy does not apply to VCA transplants.~~

12.2 VCA Allocation

VCAs from deceased donors are allocated to candidates in need of that VCA according to *Table 12-1* below.

Table 12-1: Allocation of VCAs from Deceased Donors

Classification	Candidates ~~that are~~ registered at a transplant hospital that is within this distance from a donor hospital:	And are:
1	500 NM	Blood type compatible with the donor
2	Nation	Blood type compatible with the donor

Within each classification, candidates are sorted by waiting time (longest to shortest).

~~When a VCA is allocated, the host OPO must document both of the following:~~

~~1. How the organ is allocated and the rationale for allocation~~

~~2. Any reason for organ offer refusals~~

18.1.B Timely Submission of Certain Data

Members must submit data to the OPTN Contractor according to Table 18-1.

Table 18-1: Data Submission Requirements

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Histocompatibility Laboratory	*Donor Histocompatibility* (DHS)	60 days after the DHS record is generated	Each living and deceased donor This does not apply to living VCA donors
Histocompatibility Laboratory	*Recipient Histocompatibility* (RHS)	60 days after the transplant hospital removes the candidate from the waiting list because of transplant	Each heart, intestine, kidney, liver, lung, ~~or~~ pancreas, or VCA transplant recipient typed by the laboratory
OPO	*Death Notification Registration (DNR)*	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	*Potential Transplant Recipient* (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, ~~or~~ pancreas, or VCA that is offered to a potential recipient
~~Allocating OPO~~	~~VCA Candidate List~~	~~30 days after the procurement date~~	~~Each deceased donor VCA organ that is offered to a potential VCA recipient~~

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Host OPO	*Donor Organ Disposition (Feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	*Deceased Donor Registration* (DDR)	60 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living Donor Feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	*Living Donor Feedback*	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	*Living Donor Registration* (LDR)	90 days after the Recovery Hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to VCA donor organs

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Recovery Hospitals	*Living Donor Follow-up* (LDF)	Either: • 90 days after the six-month, 1-year, and 2-year anniversary of the donation date • As determined possible by the transplant hospital during the COVID-19 emergency.	Each living donor organ recovered at the hospital This does not apply to VCA, domino donor, and non-domino therapeutic donor organs Non-submission of the full LDF is acceptable during the COVID-19 emergency.
Transplant hospitals	*Organ Specific Transplant Recipient Follow-up* (TRF)	*Either* of the following: • 90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure or as determined possible by the transplant hospital during the COVID-19 emergency • 30 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital Non-submission of the full TRF is acceptable during the COVID-19 emergency; however notifications of recipient's death or graft failure are still required during the COVID-19 emergency.
Transplant hospitals	*Organ Specific Transplant Recipient Registration* (TRR)	90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital removes candidate from waiting list	Each liver recipient transplanted by the hospital

The following member:	*Must submit the following instruments to the OPTN Contractor:*	*Within:*	*For:*
Transplant hospitals	*Waiting List Removal for Transplant*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, ~~or~~ pancreas, or VCA recipient transplanted by the hospital
~~Transplant hospitals~~	~~Candidate Removal Worksheet~~	~~1 day after the transplant~~	~~Each VCA recipient transplanted by the hospital~~
Transplant hospitals	*Recipient Malignancy* (PTM)	Either: • 30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form or • As determined possible by the transplant hospital during the COVID-19 emergency.	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital. Non-submission is acceptable during the COVID-19 emergency.
Transplant hospitals	*Transplant Candidate Registration* (TCR)	90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, ~~or~~ pancreas, or VCA candidate on the waiting list or recipient transplanted by the hospital

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN Contractor within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN Contractor may report this information. The OPO or the OPTN Contractor must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN Contractor will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

~~This policy does not apply to VCA organ offers; instead, members must document VCA offers according to *Policy 18.1: Data Submission Requirements*.~~

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