Access to Direct Acting Antiviral Therapy for Recipients of Solid Organs from Hepatitis C-Viremic Donors

Cori Edmonds, PharmD, Alicia Carver, PharmD, Josh DeClercq, MS, Leena Choi, PhD, Megan Peter, PhD, Rachel Forbes, MD, Beatrice Concepcion, MD, Kelly Schlendorf, MD, Roman Perri, MD

Quick Facts

Evaluated

91 Solid organ transplant recipients with confirmed, active donor derived HCV infection

69% Dispensed at VSP

Results

Average Patient Cost

$2 With Assistance

$8 Without Assistance

100% of Patients Approved

Median Days from Insurance Approval to First Dose

6 VSP Patients

13 Non-VSP Patients

Predictors of time in days from benefits investigation to first dose

- Filled first dose at offsite specialty pharmacy (OR=5.7; p<0.001)
- Insurance appeal required (OR=4.7; p<0.001)

VSP pharmacists are successful at helping patients access and afford HCV treatment post-transplant.

Requiring an offsite specialty pharmacy increases the time for patients to receive the first dose of medication after a benefits investigation or prior authorization has been completed.

VANDERBILT HEALTH

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Introduction

Medications to treat the hepatitis C virus (HCV) are notoriously expensive and plagued by strict insurance prior authorization (PA) criteria. Emerging data supports transplantation of organs from viremic, HCV-positive donors into HCV-negative recipients to expand the donor pool.[1,2] However, when implemented as standard practice post solid organ transplantation (SOT), prescription (Rx) access to HCV direct acting antivirals (DAAs) to treat patients who develop donor-derived hepatitis C (dd-HCV) has not been well described.

References:

1. Schlendorf KH, Zalawadiya S, Shah Ashish, et al. Early outcomes using hepatits C positive donors for cardiac transplantation in the era of effective direct acting anti viral therapies. J Heart Lung Transplant. 2018; 37:763 769.

2. Potluri VS, Goldberg DS, Mohan S, et al. National trends in utilization and 1 year outcomes with transplantation of HCV viremic kidneys. J Am Soc Nephrol. 2019;30:1929 1951.

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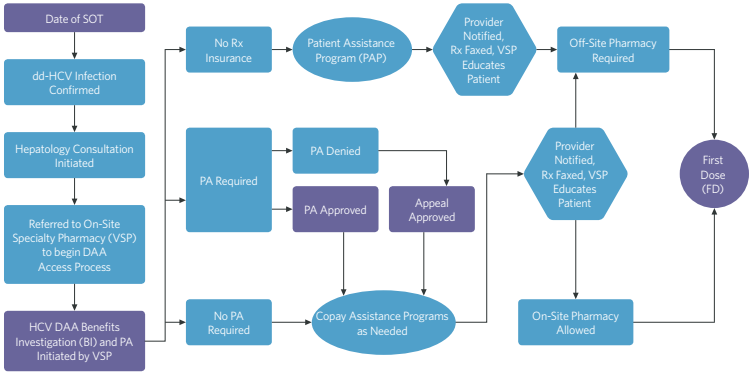
Purpose

Evaluate HCV DAA prescription access, cost, timing and barriers to first dose (FD) in solid organ transplant recipients with confirmed, active dd HCV infection post transplantation in a real world, standard practice.

Methods

Design	Single center, IRB approved, retrospective cohort review
Sample	dd-HCV solid organ transplant recipients transplanted between October 2016 and May 2019 prescribed HCV DAA therapy at Vanderbilt University Medical Center
Outcomes and Variables	HCV DAA insurance approval rates Insurance PA denial reasons Time to FD Barriers encountered from BI to FD Predictors of delay from BI to FD Copay assistance use Out-of-pocket (OOP) DAA cost
Analysis	Descriptive statistics to summarize data. Univariate proportional odds logistic regression to assess factors related to time from BI to FD.

HCV DAA Therapy Access Standard Process



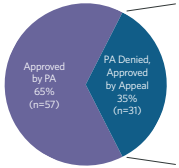
Results

Cohort Characteristics	(n=91) M [SD] or % (n)
Age (Years)	55 [11]
Gender (Male)	68 (62)
Race (White)	72.5 (66)
Genotype	
1	69 (63)
2	8 (7)
3	22 (20)
Mixed	1 (1)
Transplant Type	
Heart	52 (47)
Kidney	30 (27)
Liver	11 (10)
Heart/Kidney	4 (4)
Liver/Kidney	1 (1)
Lung	2 (2)
Insurance Type	
Government	46 (42)
Private/Commercial	54 (49)
Prescription Coverage	
Insured	97 (88)
Not Insured	2 (2)
Underinsured	1 (1)
Specialty Pharmacy Rx Dispense Site	
On-Site (VSP)	69 (63)
Off-Site (Non-VSP)	31 (28)
HCV DAA Prescribed (12 Weeks)	
Sofosbuvir/Ledipasvir	46 (42)
Sofosbuvir/Velpatasvir	13 (12)
Glecaprevir/Pibrentasvir	41 (37)
Pre-Therapy HCV Viral Load	
< 1 million	48 (44)
1 to < 25 million	26 (24)
>25 million	23 (23)
Therapy Response Rate	
Sustained Viral Response	98 (89)
Relapsed	1 (1)
Therapy not completed	1 (1)

HCV DAA Access Rates

Prescription Insurance Status	% (n)
Rx Insurance Approvals	100 (88)
PAP (No Rx Insurance) Approvals	100 (3)

Rx Insurance Approvals

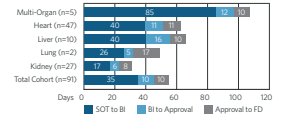


PA Denial Reasons

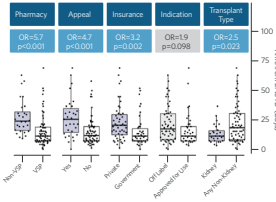
HCV DAA Access Timeline

Time Period	Median Days	IQR
SOT to FD	45	[34 - 66]
SOT to BI	28	[18.5 - 41.5]
BI to FD	16	[9 - 27]
BI to Approval	6	[4 - 12]
Approval to FD	8	[5 - 12.5]

Mean Days in Time Periods Following SOT by Organ Type



Barriers and Delays to First Dose



- In univariate analyses, time between BI and FD was significantly longer for patients who:
  - Filled their first Rx at an off site specialty pharmacy
  - Required an insurance appeal
  - Held private/commercial insurance
  - Received a non kidney solid organ transplant
- A third of patients (n=33, 36%) encountered a delay between BI to FD that was not related to a PA denial:
  - BI to Approval Period (n=9, 27%)
    - Missing clinical data for PA (n=4)
    - Delay in obtaining PA form (n=3)
    - PAP paperwork process delay (n=2)
  - Approval to FD Period (n=24, 71%)
    - Awaiting inpatient setting discharge (n=11)
    - Pharmacy Rx processing/shipping issue (n=9)
    - Patient/Provider request (n=2)
    - Insurance changed between Approval to FD (n=2)

HCV DAA Rx Cost

	Copay Assistance Required*	
	Yes	[34 - 66]
	49% (n=31)	51% (n=32)
	Mean OOP Cost	
Pre-Assistance	$2,003 [Range: $7 - $7,536]	$8 [Range: $0 - $100]
Post-Assistance	$2 [Range: $0 - $5]	Not Applicable

*On-site Pharmacy (VSP) Data Only

Conclusions

- HCV DAA therapy for dd HCV solid organ transplant patients is achievable and affordable in the outpatient setting.
- Use of an on site specialty pharmacy for the first Rx fill is associated with a significantly shorter time to FD.
- Delays to FD after referral for BI/PA initiation are more likely when insurance requires use an off site specialty pharmacy to fill the prescription, coverage is with private insurance, SOT was non kidney, and an insurance appeal after initial PA denial is required.

Edmonds C, Carver A, DeClercq J, Choi L, Peter M, Schlendorf K, Perri R, Forbes RC, Concepcion BP. Access to hepatitis C direct-acting antiviral therapy in hepatitis C-positive donor to hepatitis C-negative recipient solid-organ transplantation in a real-world setting. Am J Surg. 2021 Sep 14:S0002-9610(21)00528-6. doi: 10.1016/j.amjsurg.2021.09.005. Epub ahead of print. PMID: 34548142