Medication Access Barriers to Hepatitis C Anti-Viral Therapy following Transplantation of Hepatitis C Positive Donors into Hepatitis C Negative Recipients

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Background

- Over the past decade there has been a paradigm shift in solid organ transplantation with the use of Hepatitis C (HCV) positive donor organs for HCV negative recipients.
- This evaluation looks through the lens of insurance approval for direct acting antivirals (DAA) and the process needed for obtaining and ensuring affordability of these medications.
- While the AASLD/IDSA guidelines recommend early initiation of pangenotypic DAA therapy after organ transplant without the need to confirm recipient viral replication many centers often initiate the DAA approval process after viremia is detected due to insurance barriers.[1]
- The process for obtaining insurance approval can be both time and resource intensive and can often delay the initiation of therapy with the potential for untreated HCV related complications.

Methods

- We conducted a retrospective chart review that evaluated DAA initiation in HCV negative abdominal organ transplant recipients with HCV positive donors defined as having detectable HCV-antibody and/or HCV nucleic acid testing (NAT).
- At our institution, kidney and liver transplant recipients initiate DAA therapy as soon as possible following transplant.
- Patients are referred to hepatology once viremia is detected (first assessed on post-operative day 3) and the process for obtaining medication is then initiated immediately.

Table 1 - Demographics

Age (years)	57.8
Sex (Male)	20 (60.6%)
Total Hep C Transplanted Organs	41
Patients Requiring DAA	33
Kidney	14 (42.5%)
Liver	14 (42.5%)
Liver/Kidney	4 (12%)
Kidney/Pancreas	1 (3%)
Donor Hepatitis C Antibody/NAT Status	
No DAA Therapy	
Ab+/NAT-	7
Ab+/NAT+	1
DAA Therapy	
Ab+/NAT+	32
Ab-/NAT+	1
Medication (n=34)	
Sofosbuvir/Velpatasvir	32 (94%)
Glecaprevir/Pibrentasvir	1 (3%)
Sofosbuvir/velpatasvir/voxilaprevir	1 (3%)

Results

- From 2018-2023 forty one patients received Hepatitis C positive organs and thirty three patients received DAA due to detectable viremia (Table 1).
- All patients (100%) who received DAA were required to have a prior authorization (PA) completed.
- One patient required a retreatment due to failure of achieving sustained virologic response at 12 weeks (SVR12).
- Ten patients (30.3%) had their prior authorizations denied and required an insurance appeal. Of the PA denials, two patients to submit a second appeal before ultimately being approved.
- The overall average time to medication approval was 3 days (range 0 days – 8 days) and 4 days (1 day – 8 days) in those with a denied prior authorization. Approval time was not different based on insurance type.
- Assistance programs were used for 16 patients due to high cost for the patient despite insurance coverage and a copay was required for 15 patients (Table 3).

Table 2: Insurance Data

	All (n=33)	Commercial (n=16)	Medicare (n=7)	Medicare Advantage (n=9)	Medicaid (n=1)
Prior Auth Required	33 (100%)	16 (100%)	7 (100%)	9 (100%)	1
Prior Auth Denied/Appealed	10	5 (31.3%)	2 (28.5%)	3 (33.3%)	0
Second Appeal Required	2	1	0	1	0
Assistance Program	16	10	1	5	0
Days to Approval					
All	3 (0-8 days)	3 (0-8 days)	3 (0-7 days)	3 (0-6 days)	2 days
With Prior Auth Alone	2 (0-8 days)	2 (0-8 days)	3 (0-7 days)	3 (0-4 days)	2 days
With 1 Appeal	3 (1-6 days)	3 (1-5 days)	3.5 (3-4 days)	4 (2-6 days)	n/a
With 2 Appeals	5.5 (3- 6 days)	8 days	n/a	3 days	n/a
Reasons for Denials	Genotype needed, Brand Preferred by Plan, Renal function too low, Non-documents chronic HCV, no Fibroscore				

Table 3: Copays and Sustained Virologic Response (SVR)

Number of people with copay pre-assistance	20
Amount pre assistance	$870.43 ($3.9-$7000) /Month
Number of people with copay post-assistance	15
Amount Post Assistance	$7.5 ($2.09-$65) /month
	Patients Eligble
SVR 12 weeks	30/31 (96.8%)
SVR 24 weeks	25/25 (100%)
SVR 48 weeks	18/18 (100%)

Note: Patients were not eligible for SVR evaluation if the time following transplant was less than 12,24,or 48 weeks respectively. Data was also not received for multiple patients.

Discussion and Future Directions

- The acquisition of DAA therapy for Hepatitis C following Hepatitis C donor positive solid organ transplant remains an unnecessarily arduous process.
- Our study showed that although all patients required a prior authorization, all were able to get the medication eventually. Significant time on the part of our transplant pharmacists was necessary to achieve this outcome.
- Justification for the time required to obtain DAA for recipients can be questioned given the accepted critical need for these medications in the case of NAT positive donors, and the well documented risks involved with untreated HCV after organ transplant.
- As AASLD/IDSA guidelines do not specify the need for detectable viremia in recipients prior to initiation of DAA therapy, removing this step in obtaining approval should be considered in cases of NAT positive donors.

Linkage to Healthcare Disparities

- Prior Authorizations (PA) are the process in which an insurance company limits its services by requiring further documentation before approving a medicine or surgical procedure
- While our study highlights the prior authorization process implemented for DAA therapy with Hep C transplanted organs, this practice is prevalent throughout all of medicine.
- One Kaiser Family Foundation study showed that 22% of patients insured under Medicaid experienced prior authorization problems compared with 11% for Medicare and 15% for employee sponsored insurance.[2]
- Different medical conditions are also unfairly targeted including those with mental health diagnoses, opiate use disorder, HIV, and Hepatitis C.[3]
- To help combat these delays and disparities in care we must first highlight the problem and raise awareness of issues that the prior authorization process creates.
- Further research and legislation can aim to help restrict insurance companies ability to dictate medical care.

Sources:

1. Bhattacharya D, Aronsohn A, Price J, Lo Re V; AASLD-IDSA HCV Guidance Panel. Hepatitis C Guidance 2023 Update: AASLD-IDSA Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. *Clin Infect Dis*. Published online May 25, 2023. doi:10.1093/cid/ciad319
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