ACCESS TO DIRECT ACTING ANTIVIRAL THERAPY FOR RECIPIENTS OF SOLID ORGANS FROM HEPATITIS C-VIREMIC DONORS

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 HCV-infected donors for cardiac transplantation in the era of effective direct acting anti viral therapies.

METHODS

RESULTS

HCV DAA Therapy Access Standard Process

Date of SOT

Hepatology Consultation Initiated

Referred to On-Site Specialty Pharmacy (VSP) to begin DAA Access Process

HCV DAA Benefits Investigation (BI) and PA Initiated by VSP

No Rx Insurance

No PA Required

No Rx Insurance

Patient Assistance Programs (PAP)

Provider Notified, Rx denied, VSP Educates Patient

Off-Site Pharmacy Required

Provided Notified, Rx denied, E-Scribed, VSP Educates Patient

Off-Site Pharmacy Required

First Dose (FD)

HCV DAA Therapy Access Process

Cohort Characteristics (n=91)

M (SD) or % (n)

Age (Years)

55 (11)

Gender (Male)

68 (62)

Race (White)

72.5 (8)

Genotype

1: 69 (63)

2: 2 (87)

3: 22 (20)

Mixed: 1 (1)

Transplant Type

Heart: 52 (47)

Kidney: 30 (27)

Liver: 11 (10)

Liver/Heart: 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/Pirtelavir: 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)

Pre-Approval Rx Insurance Status

Rx Insurance Approvals

100 (88)

PAP (no Rx Insurance) Approvals

100 (3)

PA Denied

No Rx Insurance

100 (88)

PAP (no Rx Insurance)

100 (3)

PA Denied, Approved by Appeal

57 (52)

Time Period

Median Days

SOT to BI

26 [19.6-41.5]

SOT to BI

28 [16.5-41.5]

BI to FD

16 [9-27]

BI to Approval

6 [4-12]

Approval to FD

5 [3-12.5]

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Barriers and Delays to First Dose

In a univariate analysis, time between BI and FD was significantly longer for patients who:

- Paid their first Rx at an off-site specialty pharmacy
- Required an insurance appeal
- Held private/commercial insurance
- Received a non-commercial 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=27, 27%)
- Missing clinical data for PA (n=4)
- Delay in obtaining PA form (n=5)
- PAP paperwork process delay (n=2)
- Approval to FD Period (n=24, 71%)
- Denied/pending status change (n=1)
- Pharmacy Rx processing/shipping issue (n=9)
- Physician/Provider request (n=2)
- Insurance change approved before Approval to FD (n=2)

CONCLUSIONS

HCV DAA therapy for dd-HCV solid organ transplant patients is achievable and affordable in the outpatient setting. Use of 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 of 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.

HCV DAA Access Timeline

Cut off 5% or less

Pre-Assistance

$2,650

Mean OOP Cost

$0

Post-Assistance

$0

HCV DAA Rx Cost

Copy Assistance Required* Yes No

49% (n=31) 51% (n=32)

Mean OOP Cost

$0

* On-Site Pharmacy (VSP) - Data Only

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Predictors of Time in Days from BI to FD

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