NEW HEPATITIS DRUGS IN A MEDICAID SPECIAL NEEDS POPULATION-A PRELIMINARY REPORT

T Leach; J Moore; S Rambaran; E Leach; J Cohn; N Olivo; JA Ernst

OBJECTIVES

1. To report our initial experiences with direct acting antiviral (DAAs) treatments for Hepatitis C (HCV) in a HIV/HCV co-infected population.
2. To explore how real-world results compare to those reported in clinical trials.

BACKGROUND

Amida Care, a Medicaid Special Needs Plan exclusively designed for people with HIV, has been approving regimens containing DAAs since December 2013. Members in the plan have an average of 7.2 co-morbidities with the top three being; severe mental illness, active drug abuse and Hepatitis C. The Plan's overall HIV viral suppression rate approaches 70%.

With the advent of DAAs for the treatment of HCV, cure rates reported in clinical trials are well over 95% as measured by sustained virologic responses at 12 weeks (SVR12). We are reporting here initial results in the first 109 patients treated with DAAs from December 2013 through September 2014.

METHODS

We performed a retrospective record review of HIV/HCV patients receiving DAA treatment for HCV from December 2013 thru September 2014. Only patients who completed treatment and had an end of treatment viral load result or who did not complete treatment are included in this report.

HIV RNA, CD4 Cell counts, HCV RNA, HCV genotypes and fibrosis scores (when available) were collected at baseline as part of the preapproval process in patients who qualified for HCV treatment according to current guidelines (See box to right).

NY Medicaid Clinical Criteria for Initial DAA Review - Highlights

1. Adult patient age ≥18 years old; AND
2. Prescribed by a hepatologist, gastroenterologist, infectious disease specialist, transplant physician, or health care practitioner experienced and trained in treatment of hepatitis C or a healthcare practitioner under direct supervision of a listed specialist; AND
3. Patient is sofosbuvir treatment naive (no claims history or reference in medical records to previous trial and failure of sofosbuvir); AND
4. Patient has demonstrated treatment readiness and ability to adhere to drug regimen; AND
5. Baseline HCV RNA must be submitted with a collection date within the past 3 months. Prescriber must submit lab documentation indicating HCV genotype and quantitative viral load; AND
6. Patient meets the diagnosis and disease severity criteria, as follows:
   - **Evidence of Stage 3 or Stage 4 hepatic fibrosis OR**
   - Organ transplant; OR
   - HIV-1 coinfection; OR
   - HVB coinfection; OR
   - Other coexistent liver disease; OR
   - Type 2 diabetes mellitus (insulin resistant); OR
   - Porphyria cutanea tarda; OR
   - Debilitating fatigue.
7. Patient commits to the planned course of treatment (blood tests and visits); AND
8. Female patients of child bearing potential must not be pregnant; AND
9. For HIV-1 co-infected patients – No detectable viral load for the past 6 months.

Pharmacy staff monitored baseline characteristics, lab results and adherence from the time HCV treatment was requested through 12 weeks post treatment.

RESULTS

Table 1 - Treatment Status of HIV/HCV Co-infected Health Plan Members treated with DAAs December 2013 to Sept. 2014.

Total Members Treated	109	100%
Completed Therapy	**93**	**85%**
Did Not Complete Therapy	**16**	**15%**
• Medication side effects	7	6%
• Provider discontinuation	5	5%
• Member dis-enrolled	2	2%
• Member deceased	1	1%
• Member incarcerated	1	1%
Members with available data (Lab data still being collected and will be reported at a later date)	**50**	**46%**

Table 2 - Genotype of DAA Treated Members (n=50)

Genotype	Quantity	Percent
1a	**35**	**70%**
1b	**9**	**18%**
2a, 2b, 2c	**6**	**12%**
3 and 4	**0**	**0%**

Table 3 - End of Treatment (EOT) Results by Regimen and CD4 Count

Treatment Results for DAA Treated Members with a CD4 < 200 (n=3)

Treatment Regimens±	Number Treated	HCV Treatment Experienced	Treatment Naive	Fibrosis F1-F2 (n=3)	Fibrosis ≥F3-F4 (n=3)	HCV Suppression @ 1 month	End-of-treatment HCV Suppression
SOF+Riba	2	0	2	0	1	1	2
SOF+Peg+Riba	1	0	1	0	0	0	0
SOF + SIM	0	0	0	0	0	0	0
SOF+SIM+Riba	0	0	0	0	0	0	0

Treatment Results for DAA Treated Members with a CD4 = 200-499 (n=22)

Treatment Regimens±	Number Treated	HCV Treatment Experienced	Treatment Naive	Fibrosis F1-F2 (n=22)	Fibrosis ≥F3-F4 (n=22)	HCV Suppression @ 1 month	End-of-treatment HCV Suppression
SOF+Riba	7	3	4	2	3	7	7
SOF+Peg+Riba	11	4	7	1	5	11	8
SOF + SIM	4	3	1	0	4	4	4
SOF+SIM+Riba	0	0	0	0	0	0	0

Treatment Results for DAA Treated Members with a CD4 ≥ 500 (n=25)

Treatment Regimens±	Number Treated	HCV Treatment Experienced	Treatment Naive	Fibrosis F1-F2 (n=25)	Fibrosis ≥F3-F4 (n=25)	HCV Suppression @ 1 month	End-of-treatment HCV Suppression
SOF+Riba	2	1	1	0	1	2	2
SOF+Peg+Riba	17	9	8	7	4	14	17
SOF + SIM	5	2	3	1	4	4	5
SOF+SIM+Riba	1	1	0	0	1	0	1
Totals	50	22 (45%)	27 (55%)	11(22%)	22 (45%)	42(84%)	45(90%)

± Peg=peginterferon alfa-2a, Riba=ribavirin, SIM=simeprevir, SOF=sofosbuvir

CONCLUSION

Preliminary results in a Medicaid HIV/HCV co-infected population show impressive end of treatment HCV suppression rates.

This study is ongoing and final results including SVR12s will be presented at a later time.

RECOMMENDATIONS

Future follow-up evaluations of interest include:

- Assessments of treatment results by treatment regimens including daily oral-only therapies
- Expanding the evaluation to incorporate SVR-12 results
- Investigate the incidence of re-infection
- Identify potential barriers to DAA treatment for those who have not been treated. (Preliminary data is being presented in a poster at this meeting)
- Understand the impact of disease variables (CD4, treatment history and liver fibrosis score) on SVR-12 rates

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Contact: Terry Leach, Pharm D,
Vice President of Pharmacy
Amida Care, 14 Penn Plaza, 2nd Floor
New York, NY 10022 646-757-7682
tleach@amidacareny.org