

# Direct Acting Antiviral Therapies in a New York City HIV/AIDS Special Needs Plan: Uptake and Barriers

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## Objectives

There is considerable interest amongst clinical care providers in providing direct acting antiviral therapies (DAAs) to their HIV/HCV co-infected patients. However, because of the great expense and limited availability – in some settings – of DAAs it is not well understood what types of HIV patients are actually being prioritized for DAA therapy and whether current clinical practices make the most sense in terms of reducing morbidity, mortality and costs. To provide insight into these questions, we used insurance claims data from a not-for-profit Medicaid Special Needs Health Plan designed exclusively for persons living with HIV/AIDS in New York City to: (a) assess the uptake of DAAs among HIV/HCV co-infected persons and (b) compare patients receiving DAAs to those who are not and to identify potential barriers and enablers to DAA uptake.

## Methods

- Amida Care began approving claims for DAAs in December 2013.
- We examined the Amida Care claims database for demographic, clinical and pharmacy information among persons with claims consistent with chronic HCV infection (CPT-4, ICD-9, or ICD-10) during December 1<sup>st</sup>, 2013 to September 30<sup>th</sup>, 2014, and entered into the claims database through March 1<sup>st</sup>, 2015.

- T-tests and chi-square tests were used for statistical comparisons.

## Results

- N=1,756 individuals Amida Care participants had a diagnosis consistent with chronic HCV infection based on claims data during December 1<sup>st</sup>, 2013 to September 30<sup>th</sup>, 2014,
- Of these participants, 6% (n=109) received sofosbuvir (SOF) and/or simeprevir (SIM) during the study time period.
- Approval requests submitted to Amida Care by clinical care providers included evidence that all of these patients – with one exception – were receiving combination antiretroviral therapy (ART) and had HIV viral load levels below the lower limit of quantification (LLQ) of available virologic assays. The one exception was an elite controller who achieved an HIV viral load level below the LLQ without ART.
- As compared to those who did not receive SOF and/or SIM, patients treated with a DAA were significantly older (median age: 53.2 vs. 52.8;  $P=0.007$ ), less likely to have a history of AIDS (11% vs. 26%;  $P=0.0004$ ) and were marginally ( $P=0.06$ ) more likely to be male. CD4+ T-cell levels for patients who received DAA therapy were marginally higher than for patients who did not (median CD4+: 467 vs. 420;  $P=0.06$ ).

Table 1. Participants in a New York City HIV/AIDS health plan with a diagnosis consistent with chronic HCV infection, December 1<sup>st</sup>, 2013 to September 30<sup>th</sup>, 2014.

	Received DAAs (n=109)	No DAAs (n=1647)	P
Sex			0.06
Male	83 (76%)	1111 (67%)	
Female	26 (24%)	536 (33%)	
Race/Ethnicity			0.64
Black or African American	17 (16%)	310 (19%)	
White	3 (3%)	72 (4%)	
Other <sup>a</sup>	36 (33%)	538 (33%)	
Unknown	53 (49%)	727 (44%)	
History of AIDS	12 (11%)	432 (26%)	0.0004
Received opiate medication	55 (50%)	803 (49%)	0.73
	Median (IQR)	Median (IQR)	
Age	53.2 (49.6-59.1)	52.8 (47.3-57.8)	0.007
CD4+ count <sup>a</sup>	467 (399-644)	420 (232-649)	0.06

DAA: direct acting antiviral; IQR: interquartile range

<sup>a</sup> Includes Hispanics/Latinos

<sup>b</sup> CD4+ count comparisons were based on: [Received DAAs group: 33 unique participants with 93 CD4+ measurements during the study period] and [No DAAs group: 517 unique participants with 1114 CD4+ measurements during the study period].

## Conclusions

- Our data suggest that HIV clinical care providers are currently only requesting approval to treat patients with well controlled HIV and that predictions of rapid eradication of HCV from HIV patient populations may be unrealistic.
- It is now important that clinical care providers and payers begin to consider evidence-based strategies to treat HIV/HCV co-infected patients with uncontrolled HIV or other characteristics that suggest that adherence to DAAs may be <100%.