CHAIR'S CHALLENGE

UNITE TO END THE EPIDEMICS 2017-2018

Oklahoma ADAP Supports Access to Directly-Acting Antiviral Hepatitis C (HCV) Treatment

TARGET POPULATION: Oklahoma ADAP clients co-infected with HIV and HCV
LOCATION: Oklahoma
PROGRAM DESIGN: Primarily the ADAP-funded insurance program
ESTIMATED COST: $450,000
FUNDING SOURCE: Ryan White Part B and ADAP federal awards, rebates

SUMMARY

Oklahoma's two Ryan White Part C clinics are using an ADAP-funded insurance program to provide access to directly-acting antiviral hepatitis C (HCV) treatment for individuals co-infected with HIV and HCV. Thirty-five people living with HIV have used the program to access HCV treatment since 2015.

CORE ACTIVITIES

Inclusion of HCV Treatment on ADAP Formulary

Hepatitis C (HCV) treatment medications have always been included on Oklahoma's ADAP formulary. The Oklahoma ADAP provides clients assistance primarily through the ADAP-funded insurance program (i.e., through payment of health insurance premiums and prescription co-payments). Eighty-five percent of the total 2,000 ADAP clients served in calendar year 2016 received insurance assistance. The remaining 15% receive direct medication assistance through the full-pay prescription program's 340B inventory. All Food & Drug Administration (FDA)-approved HCV treatment medications, including directly-acting antivirals (DAAs) are automatically added to the ADAP formulary without restrictions for both the ADAP-funded insurance and full-pay prescription programs.

The primary medical providers for ADAP clients are located at the two Ryan White Part C clinics in Oklahoma City and Tulsa, respectively. HIV/HCV co-infected ADAP clients receiving care at the Oklahoma City Part C clinic accessed HCV DAAs through a contracted pharmacy that billed ADAP for the related prescription co-payments. The Tulsa Part C clinic utilized a local pharmacy to dispense medications; the ADAP was not billed for the HCV

DAA treatment medication co-payments. ADAP provided health insurance premium coverage for both Part C clinics' HIV/HCV co-infected ADAP clients. There were two co-infected ADAP clients who received their medical care outside of the Part C clinics.

Monitoring HCV-Related Treatment Outcomes

Clinical doctors of pharmacy (PharmDs) at the Oklahoma University (OU) Infectious Disease Institute (IDI) in Oklahoma City monitor clients' HCV outcomes (i.e., sustained virologic response (SVR)) and coordinate treatment follow-up activities. The OU IDI already had a contract in place with ADAP for monitoring clients' adherence and providing the ADAP with in-depth information and reports. As part of treatment follow-up, the PharmD shares recommendations with OU IDI providers for selection or changes to HIV antiretrovirals (ARVs) to manage drug-drug interactions prior to the initiation of HCV treatment. Patients are educated on the administration HCV DAAs and possible side effects. Clients' progress is followed as part of return visits at defined intervals (i.e., week 4 and 12 weeks after completion of therapy). Laboratory monitoring for safety and efficacy are conducted through the period of treatment and at the 12-week follow-up appointment. The program's contracted pharmacy also provides HCV DAA utilization data with the ADAP and clinical PharmDs, inclusive of the medication name, number of prescription fills, costs, and third-party payment source.

DATA

As reported within client-level data from the contracted pharmacy at the Oklahoma City Ryan White Part C clinic, 35 PLWH have accessed HCV DAA treatment medications via ADAP since 2015. Twenty-one clients accessed treatment in 2015, while 13 and three clients accessed treatment in 2016 and 2017, respectively. Thirty-four of these clients had third-party coverage: 19 via Affordable Care Act (ACA) Marketplace qualified health plans (QHPs); 12 via Medicare Part D; and three via employer-sponsored insurance. Of the 21 ADAP clients who accessed HCV DAA treatment in 2015, 16 did so with $0 copayments. In 2016 only one client had $0 copayments.

The OU IDI reported SVR laboratory assessments for 22 ADAP clients during fiscal year 2016 (April 1, 2015 – March 31, 2016): 20 received ADAP-funded HCV DAA treatment while the remaining two clients were evaluated for SVR 12 weeks after completing treatment. A total of 16 clients received post-treatment SVR laboratory assessments. Two clients did not receive SVR results as they had not yet completed treatment by the end of the program year. Four clients could not be assessed post-treatment due to being deceased, incarcerated, or moved.

For fiscal year 2017 (April 1, 2016 – March 31, 2017), the OU IDI reported SVR laboratory outcomes for 13 ADAP clients: 10 received treatment and three additional clients were evaluated for SVR 12 weeks after completing treatment. Among these clients: eight received 12-week SVR lab assessments; four did not receive SVR results as they had not yet completed treatment by the end of the program year; and one client could not be assessed after being incarcerated.

The Tulsa Part C clinical reported an additional six ADAP clients as being treated with HCV DAAs in 2015. Seven ADAP clients were reportedly treated in 2016, six of which successfully achieved SVR. In 2017, they have initiated treatment for six ADAP clients.

EVALUATION

The ADAP makes regular informal requests to the Ryan White Part C clinics for information specific to ADAP clients' access to and outcomes following HCV DAA treatment.

OUTCOMES

Results from the OU IDI clinic included outcomes for 22 clients in fiscal year 2015 and 13 in fiscal year 2016. Reports included a summary of HCV genotypes as well as a summary of patient characteristics, antiviral therapy, and treatment outcomes. Reported SVR rates demonstrate positive outcomes for ADAP clients that are comparable to rates achieved in Phase III clinical trials (i.e., greater than 96%). Further detailed outcome information was provided in the report.

The Tulsa Ryan White Part C clinic has provided the number of ADAP patients treated in their clinic for each year since 2015 with clients' SVR rates for 2016.

The ADAP program has determined the number of clients receiving HCV DAA treatment through the contracted pharmacy, including the costs associated and clients' primary third party pay source.

FUNDING & COST

Ryan White Part B and ADAP federal awards were used to support these efforts, supplemented by rebate funding. Including premiums and prescription co-payments, costs totaled $44,000 in 2015 and $364,000 in 2016. The OU IDI's HCV health outcomes reporting required no additional funding outside of the existing adherence monitoring contract. The costs for providing HCV DAA treatment medications have increased significantly with the increase in the ACA Marketplace QHPs' premiums and prescription co-payments. These costs continue to rise as Marketplace premium costs increased 60% from 2016 to 2017 alone. During the July 2016 – September 2016 quarter, ADAP started receiving 340B rebates on HCV DAA treatment medications. This will further offset costs.

STRENGTHS

- ADAP has sufficient funding available to provide access to HCV DAA treatment due to ADAP-funded insurance program implementation and rebates
- ADAP's contracts with the contracted pharmacy and the OU IDI treatment adherence activities allow for coordination of services

LIMITATIONS

- Fewer ADAP clients have received HCV DAA treatment than initially projected by the Ryan White Part C clinics
- ADAP struggles to obtain comprehensive and timely data from the Tulsa Ryan White Part C clinic as they do not fill prescriptions via the same contracted pharmacy as the Oklahoma City Part C clinic
- Health outcomes date (i.e., SVR rates) are not available for the two HIV/HCV co-infected ADAP clients that received medical care outside of the Part C clinics
- The Oklahoma City contracted pharmacy experienced issues in 2017 with clients already receiving HCV DAA treatment transitioning from Marketplace insurance QHPs to employer-sponsored insurance plans; prior authorization requirements needed to be completed to continue clients' current regimen

STAKEHOLDERS

ADAP clients receiving HCV DAA treatment medications; ADAP; providers at the Ryan White Part C clinics; and clinic-based case managers responsible for ADAP enrollment and coordination.

PROGRAM CONTACT

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