Journal of the American Pharmacists Association 58 (2018) 485–491

Contents lists available at ScienceDirect

Journal of the American Pharmacists Association

journal homepage: www.japha.org

RESEARCH

Assessment of the effect of an enhanced prior authorization and management program in a United States Medicaid program on chronic hepatitis C treatment adherence and cost

Shellie L. Keast*, Bethany Holderread, Terry Cothran, Grant H. Skrepnek

ARTICLE INFO

Article history:
Received 3 August 2017
Accepted 7 June 2018
Available online 19 July 2018

ABSTRACT

Objectives: The market for chronic hepatitis C (HCV) treatment has changed rapidly. New treatments offer high cure rates, fewer adverse effects, and shorter treatments—but also increased costs per therapy. The objective of this study was to compare adherence and cost between HCV patients included in an enhanced prior authorization and management program (PAMP) versus no intervention in Medicaid members undergoing treatment.

Design: A retrospective study using longitudinal panel data assessed differences in adherence and costs associated with implementation of the PAMP from the payer perspective. The PAMP included case management, patient education, pharmacy counseling, and medication adherence. Multivariable generalized estimating equations were used to assess associations between program and outcomes.

Setting and participants: Patients with HCV enrolled in a state Medicaid program receiving or requesting HCV treatment from January 2014 to November 2015.

Outcome measures: Outcomes included medication adherence, treatment gaps, and pharmacy and total direct costs after controlling for demographic and clinical factors between those in the PAMP and those in the preintervention period.

Results: There were 384 Medicaid members included (156 pre-PAMP, 228 post-PAMP). Overall adherence was high regardless of PAMP intervention, although an adjusted 1.086-fold increase in medication possession ratio (MPR) was observed with the program and a 2.732-fold higher odds of adherence above 80% ($P < 0.05$). Members in the program had 0.358 times lower adjusted odds of a greater than 3-day treatment gap, and pharmacy-related costs were 0.940 times lower ($P < 0.05$); no difference was observed in total medical costs ($P = 0.333$).

Conclusion: This enhanced Medicaid program was associated with increased adherence to HCV therapy, decreased treatment gaps, and decreased pharmacy-related costs compared with the preintervention period. Because challenges exist if patients fail HCV treatment or if viral resistance emerges, ensuring high adherence and persistence remains key. Continued work is needed to develop and assess enhanced management programs for this population.

Recently approved oral direct-acting antivirals (DAAs) for the treatment of chronic hepatitis C virus (HCV) offer new curative approaches with fewer adverse effects, higher cure rates, and shortened treatment durations.[1,2] The increases in efficacy and tolerability with the newer treatment regimens also correlate with changes in costs of therapies: Costs per week can range from $7000 to $12,500 depending on the product chosen.[3] In a study of HCV in Florida Medicaid patients before the introduction of newer therapies, Menzin et al. found that the mean per-member per-month (PMPM) total costs for patients with HCV and no liver disease was $1730, and it was $4927 with advanced liver disease.[4] Overall, Razavi et al. characterized the cost of HCV in the United States and found the

Disclosure: All authors disclose either employment by or contractual work for the Oklahoma Healthcare Authority. In addition, S.L.K, G.H.S., and B.H. disclose funding through an unrestricted research grant from Gilead Sciences. S.L.K. and G.H.S. acknowledge unrelated funding from Purdue Pharma for a research fellowship grant.

Funding: Unrestricted research grant from Gilead Sciences. The sponsor was not involved in the research.

Previous presentation: Academy of Managed Care and Specialty Pharmacy Annual Meeting, April 19–22, 2016, San Francisco, CA.

* **Correspondence:** Shellie L. Keast, PharmD, PhD, Assistant Professor, University of Oklahoma College of Pharmacy, CPB-222, P.O. Box 26901, Oklahoma City, OK 73126-0901.

E-mail address: shellie-keast@ouhsc.edu (S.L. Keast).

https://doi.org/10.1016/j.japh.2018.06.013
1544-3191/

Key Points

Background:

- Treatment of chronic hepatitis C virus (HCV) with new direct-acting antivirals (DAAs) is costly.
- The new DAAs offer a chance for a cure with few adverse effects and shorter treatment durations over previous therapy with the use of ribavirin and interferon.
- The cost of new DAAs has been an issue of concern for both managed care companies and policy makers.

Findings:

- Careful management of patients receiving DAAs can improve adherence and reduce gaps in therapy.
- Management may also decrease plan pharmacy costs due to reduction in incomplete courses of therapy.

total cost estimate to be $6.5 billion with an expected peak of $9.1 billion in 2024.[5] This model excluded the costs of newer therapies, although it did predict a reduction in the number of prevalent HCV cases by the year 2030 as a result of the newer therapies.[5]

Studies evaluating patient nonadherence with DAAs for the treatment of chronic HCV are limited.[6,7] No specific adherence threshold has been defined, although nonadherence is considered to be a factor associated with reduced clinical cure as measured by sustained virologic response (SVR).[6-8] Adherence thresholds have been defined in other antiviral classes similar to DAAs, such as highly active antiretroviral therapy (HAART) used for human immunodeficiency virus (HIV) suppression. HAART adherence levels of 95% or greater are recommended to sustain virologic suppression and decrease the risk of viral resistance. Less is known about the number of gap days a patient can miss while on HAART therapy before resistance emerges, although a study conducted by Smith found the number of doses that a patient could miss before resistance developed to be as low as 1 (16-hour gap) depending on medication selection, treatment experience and duration, and other host and viral factors.[9] The effect on treatment gaps and nonadherence leading to development of HCV resistance to DAAs is largely unknown. The new HCV DAAs are supplied in a quantity sufficient for 28 days of therapy; a gap of 3 days per 28-day period accounts for a nonadherence threshold of 10.7% or an adherence threshold of approximately 90%. Because there is not an established gap length or adherence threshold for DAA therapy, understanding the impact of gaps in therapy and nonadherence to DAAs is critical to effective clinical cure of HCV. Notably, heterogeneity across viral genotypes, previous treatments, and liver disease advancement may create wide variability in treatment patterns and responses.[10]

The high costs of the new regimens have increased short-term medical or pharmacy budgets, emphasizing the potential importance of patient adherence, successful treatment completion, and cure, if the outcome of long-term cost reduction is to be met.[5,7,11] Previous programs evaluating HAART adherence among Medicaid enrollees have shown a benefit or potential for intervention to improve clinical and economic outcomes. Zhang et al. analyzed Medicaid claims data from 14 states to compare the effect of different levels of adherence to HAART on clinical and economic outcomes.[12] Increased adherence demonstrated improvements in survival and lower nondrug Medicaid expenditures. The authors called for further research to identify effective interventions for improving adherence on a population scale.[12] Similarly, Hirsh et al. evaluated a pharmacist-led medication therapy management (MTM) program's effect on patient adherence to HAART in the California Medicaid population.[13] The program consisted of pharmacist appointments, weekly telephone follow-up, and drug packaging to improve adherence. Results revealed a greater percentage of patients enrolled in the program to have a medication possession ratio (MPR) of 80% or greater to HAART regimens (69.4% vs. 47.3%; $P < 0.001$), and projected costs for inpatient services were lower for program participants ($3083 ± $293 vs. $5186 ± $300; $P < 0.001$).[13]

Objective

The objective of this research was to compare adherence and cost between hepatitis C virus (HCV) patients included in an enhanced prior authorization and management program (PAMP) versus no intervention in Medicaid members undergoing treatment.

Methods

Study design overview

This retrospective study used longitudinal panel data to assess measures of medication adherence and direct medical costs from the perspective of the payer before and after implementation of an enhanced PAMP for patients being treated for HCV in a state Medicaid population. The time frame for the study was January 1, 2014, through November 30, 2015 (Figure 1), with the implementation of the PAMP program occurring on July 1, 2014. Paid Medicaid pharmacy claims, outpatient and inpatient medical claims, and clinical data were collected and used to compare the outcomes between periods (before and after PAMP implementation) among Medicaid beneficiaries. Records were deidentified after linking diagnostic and prescription records. The Institutional Review Board for the University of Oklahoma Health Sciences Center along with the Oklahoma Health Care Authority (OHCA), the administrator of the Oklahoma Medicaid program, approved this research.

Prior authorization patient management program description

Management of HCV medications was not allowed by Oklahoma law, preventing prior authorization (PA) or