ABSTRACT

TITLE: Incidence and Determinants of Denial of DAA Treatment for Chronic HCV Infection by Insurance Type During the First 6 Months of the Modern HCV Treatment Era

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ABSTRACT BODY: Abstract Body (Late-Breaking Submission): Background: The high costs of direct-acting antiviral (DAA) agents to treat chronic HCV infection have resulted in denials and delays in the receipt of these therapies. We sought to: 1) determine the incidence and determinants of denial of a DAA prescription among US chronic HCV-infected patients, according to type of insurance (US Medicaid, US Medicare, commercial insurance), and 2) ascertain the time to DAA prescription fill.

Methods: We conducted a prospective cohort study among chronic HCV-infected patients who had a DAA prescription submitted between November 1, 2014 and April 30, 2015 to two specialty pharmacies (Burmans Specialty Pharmacy and Penn Presbyterian Medical Center) serving PA, NJ, DE, and MD. The incidence of absolute denial of the prescription, defined as no fill (even after appeal), was calculated for the overall cohort and by insurance type. Multivariable logistic regression was used to determine adjusted odds ratios (ORs) with 95% confidence intervals (CIs) for associations between patient characteristics and absolute denial. Hypothesized determinants of absolute denial included insurance type, absence of cirrhosis, and HIV coinfection. For all approved prescriptions, we determined the time to fill, defined as the interval between the date of prescription and date of approval, by type of insurance.

Results: Among 2,350 patients prescribed a DAA regimen (504 covered by Medicaid; 810 by Medicare; 1,036 by commercial insurance), 375 (16.0%) received an absolute denial (genotype 1: 15.2%; genotype 2: 17.7%; genotype 3: 31.6%; p<0.001). The most common reasons for absolute denial were insufficient information to assess medical need (133 [35.5%]), lack of medical necessity (125 [33.3%]), and positive alcohol/drug screen (15 [4.0%]). Prescriptions were more commonly denied for patients covered by Medicaid (232 [46.0%]) than by Medicare (40 [4.9%]; p<0.001) or commercial insurance (103 [9.9%]; p<0.001). Among the overall cohort, Medicaid coverage (OR=8.97 [6.46-12.44]), absence of cirrhosis (OR=3.70 [2.48-5.52]), and HIV coinfection (OR=3.31 [1.28-8.56]) were independently associated with absolute denial. The median time to DAA prescription fill was longer for persons with Medicaid (23 days) than with Medicare (14 days; p<0.001) or commercial insurance (14 days; p<0.001).

Conclusions: Among chronic HCV-infected patients prescribed DAA therapy, 16% were denied by their insurance carrier. For Medicaid patients, 46% were denied DAA therapy, and they had a longer time to fill than those with other insurance. Medicaid programs should seek to increase access to DAA agents for chronic HCV-infected patients. (No Image Selected)

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