

REAL-WORLD OUTCOMES IN PATIENTS WITH CHRONIC HEPATITIS C VIRUS INFECTION AND SUBSTANCE ABUSE DISORDERS TREATED WITH GLECAPREVIR/PIBRENTASVIR FOR 8 WEEKS: A POOLED ANALYSIS OF MULTINATIONAL POST-MARKETING OBSERVATIONAL STUDIES

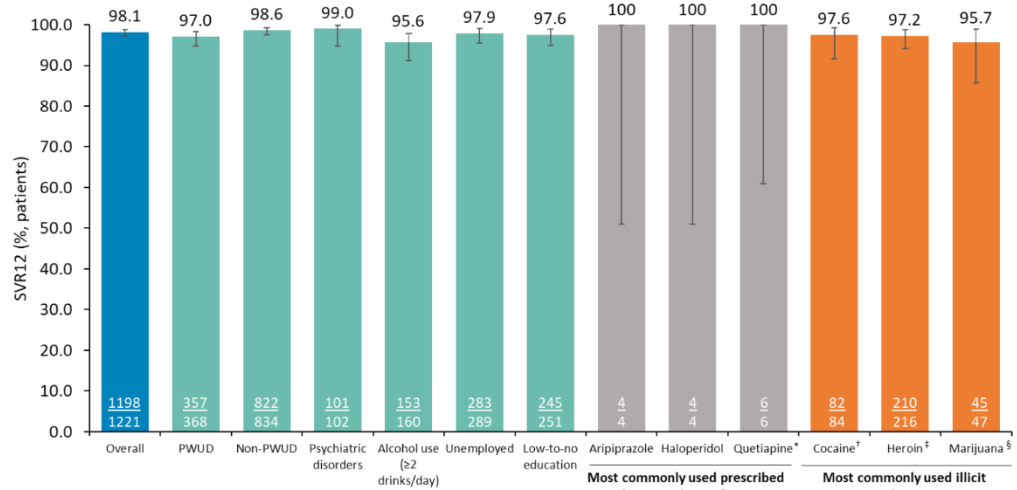
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Background: Hepatitis C virus (HCV) affects >50% of people who inject drugs. To meet World Health Organization 2030 HCV elimination targets, people who use drugs (PWUD) are a critical population to reach and provide access to treatment. Glecaprevir/pibrentasvir (G/P) is approved for treatment of adults with chronic HCV genotype (GT)1–6 infection, with a label now including 8-week treatment for treatment-naïve (TN) patients with compensated cirrhosis (CC). Despite data demonstrating G/P effectiveness in PWUD, barriers to treatment persist, including stigma, risk of reduced treatment compliance, and thus, effectiveness. Shorter therapy durations could potentially improve outcomes in such patients. This analysis examined the real-world effectiveness and safety of 8-week G/P in PWUD and other historically underserved patient groups.

Methods: Data from TN patients (without cirrhosis/with CC) prescribed 8-week G/P were pooled from 9 countries (13 Nov 2017–02 Oct 2019). The percentage of patients who achieved sustained virologic response at post-treatment Week 12 (SVR12) was assessed overall/by subgroup. Illicit drug use was patient reported.

Results: Of 1423 patients prescribed G/P for 8 weeks, 452 (31.8%) had a self-reported history of any illicit drug use (PWUD), 120 (8.4%) had psychiatric disorders, 192 (13.5%) had a history of alcohol use (≥ 2 drinks/day), 363 (25.5%) were unemployed, 312 (21.9%) reported low-to-no education. The most commonly used prescribed psychotropic drugs with a potential interaction with G/P were quetiapine (0.5%), haloperidol (0.3%), and aripiprazole (0.3%). The most commonly used illicit drugs in PWUD were heroin (58.7%), cocaine (22.8%), and marijuana (12.8%). SVR12 rate was 98.1% (1198/1221) overall, 97.0% (357/368) in PWUD and $\geq 95.6\%$ across subgroups (Figure). There was 1 G/P-related serious adverse event.



Reasons for virologic failure

Reasons for virologic failure	Overall	PWUD	Non-PWUD	Psychiatric disorders	Alcohol use (>=2 drinks/day)	Unemployed	Low-to-no education	Most commonly used prescribed psychotropic drugs of interest			Most commonly used illicit drugs		
On-treatment virologic failure	6	1	5	1	2	2	2	0	0	0	1	0	0
Relapse	9	4	5	0	1	1	0	0	0	0	0	2	0
Discontinuation of treatment	3	2	1	0	1	1	2	0	0	0	1	1	1
Missing SVR12 data	2	2	0	0	1	1	2	0	0	0	0	2	1
Other	3	2	1	0	2	1	0	0	0	0	0	1	0

Conclusion: Across a variety of real-world clinical settings, 8-week G/P treatment was highly effective and well tolerated in HCV-infected PWUD and other historically underserved patients.

Error bars Error bars represent 95% confidence intervals. Data are from the core population with sufficient follow-up.

*An additional 4 TN/TE patients taking quetiapine received G/P for 12 weeks; all (100%) achieved SVR12. †An additional 22 TN/TE patients taking cocaine received G/P for 12 weeks; all (100%) achieved SVR12. ‡An additional 44 TN/TE patients taking heroin received G/P for 12 weeks; all (100%) achieved SVR12. §An additional 10 TN/TE patients taking marijuana received G/P for 12 weeks; all (100%) achieved SVR12.

PWUD, people who use drugs; SVR12, sustained virologic response at post-treatment Week 12; TE, treatment-experienced; TN, treatment-naïve.

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