February 27, 2020

Director Maureen Corcoran
Ohio Department of Medicaid
50 West Town St, Suite 400
Columbus, OH 43215

Dear Director Corcoran,

This letter is submitted on behalf the National Viral Hepatitis Roundtable (NVHR) and the below signed Ohio-based clinicians to request changes to the prior authorization criteria for hepatitis C virus (HCV) direct acting antivirals (DAAs).

Current prior authorization criteria for HCV DAA's are in direct conflict with guidance from the Centers for Medicare and Medicaid Services, which has stated that such criteria violate section 1927(b) of the Social Security Act. The restrictions also go against nationally developed medical guidelines for treatment of HCV by the *American Association for the Study of Liver Disease* and the *Infectious Disease Society of America* (*AASLD/IDSA*, *available at www.HCVguidelines.org*).

1.) *Specialist requirement*: Requiring an infectious disease or gastroenterology/hepatology specialist to prescribe or consult on every prescription for HCV therapy is not warranted given the ease and simplicity of treating most patients. According to IDSA/AASLD guidance, ***"the short duration of treatment and few serious adverse events associated with (HCV) DAA therapy present an opportunity to expand the number of midlevel practitioners and primary care physicians engaged in the management and treatment of HCV infection."*** Requiring treatment by or in consultation with a specialist provider is placing undue burden on persons with hepatitis C living in underserved areas, particularly those in rural areas where patients may have to travel great distances to reach a specialist. Moreover, it is unfairly driving patients away from the care of rural primary care providers and placing an undue burden on specialists.

2.) *Substance use:* Requiring screening for substance or alcohol use is not based on clinical evidence. According to IDSA/AASLD guidance, ***"There are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete HCV therapy."*** Any concerns that persons who inject drugs may be nonadherent have been countered by several studies which have demonstrated high adherence and low rates of reinfection. Given that unsafe injection drug use drives most new HCV infections, scaling up HCV treatment among persons who use drugs represents an opportunity to positively impact HCV incidence; a benefit clearly outlined in a report on viral hepatitis elimination by the National Academies of Sciences.

Moreover, requiring that patients demonstrate sobriety unfairly places additional burden on, and limits access to treatment for, persons with a comorbid medical condition. We understand that ***denying life-saving HCV treatment to persons with substance use disorder is a violation of Americans with Disabilities Act***. Specifically, Section 504 of the 1973 Rehabilitation Act prohibits discrimination against people with disabilities in programs that receive federal financial assistance.

3.) *Managed care parity*: Several of the Ohio Medicaid Managed Care plans are implementing restrictions on HCV treatment that are more severe than those policies published by Ohio Medicaid Fee-For-Service (FFS) policies. According to the guidance on the topic of HCV DAA parity originating from Centers for Medicare and Medicaid Services, which was sent to Ohio Medicaid in November of 2015: "CMS reminds states that the drugs under the approved state plan must be available to individuals enrolled in Medicaid managed care arrangements…[C]onsistent with the regulation at 42 CFR §438.210, services covered under Medicaid managed care contracts (with MCOs, prepaid inpatient health plans, and prepaid ambulatory health plans) ***must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services for beneficiaries under FFS Medicaid***."

Hepatitis C is one of the most important public health issues facing Ohio. Between 2013-2018, there were an estimated 89,600 persons living with hepatitis C in the state, more than 4x the number of people living with HIV. Unfortunately, efforts to stem new infections have been hampered by limited penetrance of curative therapy into communities with ongoing transmission. Ohio has observed increase incidence in new hepatitis C cases in recent years associated with unsafe injection drug use.

The lack of treatment access for persons who use drugs has dire downstream consequences. In 2018 alone, there were at least 2,167 newborns exposed to hepatitis C during birth in Ohio—an indication that women of child-bearing age are not accessing curative treatment. And liver cancer, which is caused primarily by hepatitis C, has claimed the lives of increasing numbers of Ohioans every year. In the past decade, the age-adjusted rate of liver cancer deaths in Ohio has increased by 32%, while the rate for all cancers has decreased. Treatment of hepatitis C is an evidence-based method to decrease the likelihood of developing liver cancer.

The current Medicaid access policies are in direct conflict with these public health priorities and undermine our state's urgent need to reduce the burden of viral hepatitis and liver cancer. We would like to share with you the expertise of this group as well as their personal experiences navigating Ohio Medicaid policies on this issue by requesting a meeting at your earliest convenience.

Thank you for your consideration. We look forward to a response from your office within 30 days receipt of this letter.

Regards,

Lauren Canary, MPH
Director, National Viral Hepatitis Roundtable
Lauren@nvhr.org

Signature	Name/Title
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____