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Secretary Laura Herrera Scott
Secretary of Health, Maryland Department of Health
201 W. Preston Street, 5th Floor
Baltimore, MD 21201
laura.herrerascott@maryland.gov

Re: Hepatitis C Prior Authorization Criteria

Dear Secretary Herrera Scott,

Thank you for meeting with the Maryland Hepatitis Coalition (MHC) about the delays, denials, and interruptions to care that current prior authorization (PA) requirements are causing patients living with hepatitis C virus (HCV). We deeply value our partnership with Maryland Medicaid and the changes that the State has made over the years to expand access to hepatitis C treatment. Today, primary care providers across Maryland are safely and successfully curing patients living with hepatitis C with 8 to 12 weeks of oral medication. However, our ability to cure ALL patients living with hepatitis C continues to be hindered by PA. To realize our shared goals of health equity and hepatitis C elimination, **we urge Maryland Medicaid to align treatment policies with the standard of care and remove the PA requirement for direct-acting antivirals.**

To date, 23 state Medicaid programs have removed PA requirements for most patients entirely, including the District of Columbia and Virginia [1]. The PA requirement in Maryland creates confusion for providers who care for patients across the DMV area. It also leaves Maryland in the bottom 50% of state Medicaid programs' HCV treatment policies (stateofhepc.org), stagnating our pursuit of eliminating a preventable, curable infectious disease.

In reviewing the literature, the overwhelming majority of prior authorizations were ultimately approved by payers. Yet, they delay care for our most marginalized and disproportionately impacted communities such as people who are unhoused, people who use drugs, and people of color from receiving timely access to lifesaving treatment. Studies have found high rates of denials of 29-63% that delay medication approval, a median of 60 days in one study, with almost all PAs ultimately being approved [2, 3]. Ultimately, the only people not approved were those who were lost to follow up, lost insurance coverage, or decided not to pursue treatment [2, 3]. Patients who are lost in these days and weeks between PA submission, denial, appeal, and approval are disproportionately vulnerable populations. **As such, prior authorization removal would be an early health equity win for Governor Moore's administration.**

Prior authorizations also delay complex, expensive care, such as transplant. Transplant studies showed that up to 24 to 35% of PAs required an appeal, despite 96 to 100% of requests being approved. Even when the PA process was started immediately after transplant, the median time from transplant to treatment initiation ranged 28 to 45 days [4, 5, 6]. The clinical and financial costs of transplant care are piled on top of the financial costs of untreated chronic hepatitis C, which can lead to severe and costly forms of liver disease, which can be as costly as $47,000 per patient per year [7].

Maryland Medicaid's current prior authorization process continues to be inconsistent and administratively onerous, resulting in confusion for providers and delays or denials of treatment for patients. Some managed care organizations have particularly challenging prior authorization forms, requiring different forms for each medication and answers to more than 30 questions. Additionally, Maryland Medicaid requires documentation of chronic HCV infection and requires that labs such as viral load and genotype be collected within a certain timeframe, the timeframes of which vary by plan. These requirements do not align with the standard of care established by the American Association for the Study of Liver Disease and the Infectious Disease Society of America (AASLD/IDSA) guidelines (hcvguidelines.org).The inconsistency in eligibility and documentation requirements increase the likelihood that the prior authorization may be denied, often leading to multiple visits and further delaying treatment. Prior authorizations place an undue administrative burden on prescribers, which takes away time and resources from other life-saving care. A study in Rhode Island found that the prior authorization process took 45-120 minutes per patient, and longer with a protracted denial and appeals process [8]. This administrative burden often requires dedicated staff, which many healthcare facilities do not have the resources to provide [9].

Despite the intended purpose to facilitate guideline-adherent therapy, prior authorizations continue to be a significant barrier to accessing HCV treatment in Maryland, (a) disproportionately affecting vulnerable patient populations and exacerbating health inequity; (b) delaying time-sensitive medications and increasing risk of hepatocellular carcinoma, liver failure, and death; (c) increasing the likelihood of loss to follow up before treatment and therefore continuing HCV transmission, ; and (d) requiring significant resources by clinics and Medicaid to submit and evaluate prior authorizations. With the AASLD/IDSA Simplified Treatment Algorithm, Maryland prescribers can safely and easily provide these life saving cures to all HCV patients, without the need for prior authorization. More than 20 states have recognized that eliminating this burden allows prescribers to dedicate more time to clinical services and instead leverage the dispensing pharmacists' clinical knowledge and drug-drug interaction software used daily for other chronic conditions to confirm the appropriateness of therapy. **We urge Maryland Medicaid to follow their lead by aligning treatment policies with the standard of care and removing prior authorization for direct-acting antivirals.**

We appreciate the State's efforts to date and your attention to this matter. We would welcome the opportunity to partner on this important next step in HCV elimination. Should you have any questions, please contact Sarah Kattakuzhy (skattakuzhy@ihv.umaryland.edu) and Amanda Rosecrans (amanda.rosecrans@baltimorecity.gov).

Sincerely,

Maryland Hepatitis Coalition

CC: Ryan Moran, Deputy Secretary for Health Care Financing & Medicaid Director
Nilesh Kalyanaraman, Deputy Secretary for Public Health Services
Tricia Roddy, Deputy Medicaid Director
Lisa Burgess, Chief Medical Officer for Health Care Financing Administration
Peter DeMartino, Director of Infectious Disease Prevention & Health Services Bureau

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