September 28th, 2016

A Letter to the Members of the Oregon P&T Committee and the Oregon Health Authority Regarding Proposed Hepatitis C Treatment Restrictions

I would like to first offer my appreciation for taking some meaningful steps toward providing access to hepatitis C drugs in the state of Oregon. The class update review[1] is well researched and cited, and clearly a lot of thought went into these recommendations. The report recommends lowering fibrosis restrictions to Metavir 2 (F2), allowing treatment for patients with substance abuse disorders if they engage with an addiction specialist, and allows non-subspecialty providers to treat F2 if they have some documentation of experience. While these changes will relinquish Oregon from the notorious distinction of being one of the most restrictive states in the country, it in no way brings us in conformity to CMS Guidelines[2] or avoid impending litigation. More importantly, the persistent treatment provider restrictions, substance abuse disorder limitations, and fibrosis criteria will untenably limit access to treatment without an evidence basis and will lead to significant, unnecessary hepatitis C related morbidity and mortality.

The OHA class update report does well in outlining multiple guideline recommendations (AASLD, IDSA, WHO, VA) regarding who should treat, even mentioning that all guidelines suggest non-subspecialists (hepatology / infectious disease) should be allowed to treat except in situations of decompensated cirrhosis or other complicating factors such as HIV/Hepatitis B co-infection. The CMS letter to state Medicaid programs underscored these guidelines, urging states to drop provider restrictions. However, without explanation as to why, the recommended prior authorization (PA) criteria maintained requirements for subspecialty referral for all but F2 patients, requiring patients with F3-4 to be referred to a specialist irrespective of evidence of decompensation. I remind the members of the committee that decompensated cirrhosis is a clinical diagnosis that cannot be made by any form of fibrosis stratification. These recommendations (PA criteria 8 and 9[1]) have no basis in the literature and should be removed without stipulation.

A similar unexplained leap in reasoning occurs in the report's discussion of fibrosis restrictions. After outlining multiple national and international guidelines suggesting that *all patients with hepatitis C* should be offered treatment with a novel direct-acting antiviral (DAA) medication, it then goes on to recommend treatment for patients with metavir fibrosis scores of two or above. The people of Oregon deserve some explanation for this discordance. This is especially true because the report demonstrates some profound misunderstandings of the utility of indirect markers of fibrosis. Some blood-based tests, such as Fibrosure, are reasonably good at ruling out clinically significant fibrosis (defined as F2-4), with a negative predictive value of 91% in a population with F2-4 prevalence of 38%.[3] **That seems reasonable until we apply these operating characteristics to the Oregon Medicaid population; we will likely inappropriately under-classify and therefore inappropriately deny treatment to 1000 or more patients at any given time**. Liver elastography (fibroscan), on the other hand, is only really validated in separating F3 and above from lesser fibrosis. When the above is combined with the added complexity and limited availability of these tests, the net effect will be inappropriate delay or prevention of treatment for thousands of Oregonians.

September 28th, 2016

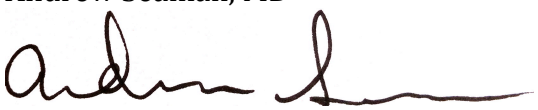
The report's maintenance of prior substance abuse restrictions is perhaps most concerning. There are no data, even from the interferon era, that suggest we should not be treating our patients with a diagnosis of substance abuse disorders. The authors again astutely outline the guidelines and evidence in support for treating hepatitis C in people suffering from alcohol use disorder and then, without explanation, require that all such patients be under the care of an addiction specialist. They describe national and international guidelines recommending that people who inject drugs (PWIDs) be *prioritized* for hepatitis C treatment, and then recommend formal barriers to treatment in this specific population. The PA requirements even suggest that all patients *who carry a substance abuse disorder diagnosis*, regardless of how recently active, must be actively treated for their addiction. This would provide huge barriers to treatment even in Multnomah County, where access to treatment is reasonable by national standards. In rural communities, it would be prohibitive. Hepatitis C reinfection in PWIDs is a real concern, if overstated and not yet quantified in the DAA age. However, readiness to treat in patients who suffer from a substance abuse disorder is a clinical assessment based on the myriad complexities of a *human being's life*, not off the distant, implicit bias-driven guidelines of a payer.

Members of the committee, we have a singular opportunity to wipe out the single largest infectious disease epidemic facing this country, and we are sitting on our hands. In many ways, these hands that wrote decades of opiate prescriptions to addicts are stained with the blood of this epidemic. We have a moral obligation to treat our community afflicted by this disease. We also have a legal obligation to treat, given that no viable alternatives exist, as dictated by the Social Security Act, section 1927(d)(4).[2] Several states, including nearby Washington, have been successfully sued for restricting access to treatment based on non-evidence-based criteria outlined in this letter and maintained in your current recommended PA criteria.[4] Oregon, too, has litigation building quietly in the background; this must be included in the conversation surrounding cost of treatment coverage.

While only nominally mentioned in the report, cost concerns inhabit every unexplained gap between guidelines and PA recommendations. There is no doubt that the cost is concerning. But we have decided as a society that we pay for treatments based on *cost-effectiveness* rather than cost, and these are incredibly cost-effective therapies.

Whether the committee drops restrictions today or the courts do so via more expensive means tomorrow, these changes are coming. Let us accept this, allow our providers to do their jobs, and move the conversation towards how we are going to pay for it.

Andrew Seaman, MD



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September 28th, 2016

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2) ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS. https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf. Accessed 9/28/16.
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Public Comment
HCV Antivirals Class Update and Treatment Guidelines

OSU Drug Use Research and Management Program
Oregon Drug Use Review / Pharmacy & Therapeutics Committee
September 29, 2016

The Caring Ambassadors Program is a national, nonprofit, advocacy organization based in Oregon City, Oregon. We respectfully submit our written comment on the current criteria and suggested update to the current Hepatitis C PDL class for treatment of Chronic Hepatitis C Virus (HCV). **We ask that Oregon's Medicaid program allow full access to all FDA approved hepatitis C direct acting agents by placing all these medications on the Preferred Drug List (PDL). This will allow medical decisions to be made between provider and patient, and will remove the current restrictions in place limiting patient access to these medications in accordance with the Center for Medicaid and CHIP Services' November 5, 2015 guidance sent to all state Medicaid programs.**

Nine months ago, I testified on this same issue and nothing has been changed, accept many more Oregonians have been refused treatment and many have died.

CMS Guidance

On November 5, 2015, CMS issued guidance to remind state Medicaid programs of their obligation to cover all FDA approved medications manufactured by companies participating in Medicaid rebate program, and any limitations must be based on clinical outcomes.

CMS stated they are concerned:

"that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4. Certain states are also requiring a period of abstinence from drug and alcohol abuse as a condition for payment for DAA HCV drugs. In addition, several states are requiring that prescriptions for DAA HCV drugs must be prescribed by, or in consultation with specific provider types… As such, the effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs."

They are specifically referring to OREGON in this letter. CMS has asked states to comply with the Patient Protection and Affordable Care Act or be in jeopardy of **violating the law.** Opening up just to F2 and above **still does not comply** with this release. Other states that previously implemented these restrictions are either changing them or may be facing legal action from their citizens. Just as Oregon will be as the Oregon Law Center is in the process of putting together a suit on behalf of Oregonians denied the cure.

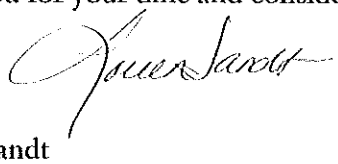
The CMS guidance also discusses the importance of following the most appropriate clinical guidelines in making treatment decisions. Two leading expert organizations, the American Association for the Study for Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), have recently updated their treatment guidelines, *"Recommendations for Testing, Managing, and Treating Hepatitis C."* They concluded that the treatment for hepatitis C would benefit nearly all of those who are chronically infected and the goal should be to treat all patients as promptly as feasible to improve their health and to reduce hepatitis C transmission. The professional guidance for treating hepatitis C is clear—**treatment is recommended and beneficial for all patients with hepatitis C, unless they have a short life expectancy. Your claim that there are no non-specialist members is false. Daniel Raymond, Andrew Reynolds, and Tracy Swan are all community members.**

You claim there is no direct evidence that treatment with antiviral therapy for CHC leads to improved long-term clinical outcomes of HCC, liver transplantation and mortality. However there several studies that show among HCV-infected persons, SVR is associated with a more than 70% reduction in the risk of liver cancer (hepatocellular carcinoma [HCC]) and a 90% reduction in the risk of liver-related mortality and liver transplantation. (Morgan, 2013); (van der Meer, 2012); (Veldt, 2007)

Your own research revealed no data to support a specific minimum length of abstinence from illicit substances or alcohol before treatment, nor are they less likely to be cured. Yet the proposed guideline calls for them to be enrolled in a treatment program under the care of an addiction specialist — there is no substantiated reason for this exclusion and adopting it will bar many of the patients most in need of treatment from being cured of their virus. This exclusion is not in line with the guidelines of AASLD. The State of Oregon is currently guilty of discriminating against its own most marginalized citizens.

With many new treatments now available, and more soon to come, we have a chance to halt this disease in its tracks; but not if we to discriminate against people accessing the Oregon Health Plan. **We are requesting that you remove the current access restrictions and allow doctors and their patients to decide the right course of therapy so that the Oregon Health Plan will be in accordance with the CMS guidance, and all Oregon Medicaid beneficiaries with hepatitis C can gain access to the hepatitis C cure medications in a timely fashion.** Denying treatment to Oregonians who can be cured of their virus and creating a new population of patients is both a costly and a deadly path for all concerned.

Thank you for your time and consideration.



Lorren Sandt
Executive Director
Caring Ambassadors Program

Oregon Pharmacy and Therapeutics Committee
September 29, 2016

Public Comment
Re: Hepatitis C Direct-acting Antivirals (DAA)

CCO Oregon is an independent non-profit member association that aims to be shaped by and to serve all stakeholders that touch coordinated care in Oregon. Our purpose is to support the delivery of exceptional care at reduced costs while promoting the health and well-being of Oregonians. This is primarily accomplished through a variety of workgroups focused on a topic related to coordinated care.

The Pharmacy & Therapeutics Committee's mission is "To evaluate available evidence-based research using a transparent process to encourage safe, effective, and financially sustainable drug use policies that maximize access to high value medications for patients served by the Oregon Health Plan and other health care programs under the Oregon Health Authority." The recommendations of this group have the potential to impact local CCOs and we thank the committee for the opportunity to provide comment today.

Safe:

Patient safety is an important consideration with any new medication. Since the clinical trial population excludes several comorbid conditions, there is limited safety data in HCV-infected individuals with many chronic diseases and history of substance use. The US Food and Drug Administration notice dated October 22, 2015 is an example, which requires the manufacturer of Viekira Pak and Technivie to include information about serious liver injury adverse events. There is also limited drug-drug interaction data, which may cause harm or impact the effectiveness of the therapy. This was seen with addition of amiodarone as a potentially dangerous drug-drug interaction after the approval of Sovaldi. There is potential for other discoveries with newer agents that will be used to treat HCV and as the populations treated with these novel drugs expands beyond that of the study populations.

Effective:

Our primary objective, in treating HCV-infected individuals, is effective sustained virological response (SVR) at 12 and 24 weeks post therapy with low incidence of adverse events, treatment failure, and reinfection. We are concerned that there is limited data available regarding SVR for patient populations that were excluded from clinical studies.

Additional considerations to enhance effectiveness include an adequate provider network and robust case management programs designed to follow HCV patients longitudinally throughout their course of care to monitor, measure, and support patients while mitigating potential treatment

failure due to co-morbid diseases using a biopsychosocial approach. Providing holistic and coordinated care will help CCOs to meet the objective of a high SVR.

Financially Sustainable:

CCO Oregon supports the treatment of HCV-infected individuals, however, there needs to be adequate resources, funding, and workforce to address the needs of our entire population. We recommend that DAA therapy be prioritized for patients with advanced cirrhosis and fibrosis or in those with extrahepatic manifestations. If a CCO is to treat additional patients, this may not be sustainable if the sum of taking care of the HCV obligations and all the other health care obligations is not adequately funded which would then mean HCV treatment was being prioritized and take resources away from other services.

We are reminded by the CMS Program Notice date November 5, 2015 titled "Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs" of the common obligations the State of Oregon, the CCOs, and additional key stakeholders share to treat and eradicate Hepatitis C. Before we expand treatment to HCV-infected individuals stage F2 and above, we need to ensure that there is a pathway to a sustainable funding source and robust HCV treatment infrastructure that is able to increase in scale to provide safe, effective therapy while not jeopardizing our larger obligations to meet the healthcare needs of the populations that we serve. Most important, we need to make sure that those at highest risk continue to have access to appropriate therapy.

CCO Oregon believes in the efficacy of the coordinated care model. The rising costs of DAA and other medications are forcing CCOs to allocate additional resources to pharmacy budgets and away from other programs. Anecdotally, for one individual CCO treating the HCV-infected at stage F2 and above patients would require 17% of the global budget. If this continues, CCOs will need to have access to supplemental funds for these emerging medications or have alternatives for paying for these medications.

Oregon CCOs have created remarkable and innovative services for their local communities. We want this work to continue, however, this may not be possible if the CCO budget has a growing pharmacy component taking resources away from other services, therefore, we respectfully request that this committee take into consideration when providing recommendations to the Oregon Health Authority the impact the decisions have on local CCOs in providing services to their communities, and without sustainable funding mechanisms for high cost medications, many services may have to be de-funded.

Thank you for the opportunity to provide comment today.

Sincerely,

CCO Oregon

CCO Oregon

UHA
Umpqua Health Alliance
AN ARCHITRAVE HEALTHCARE SERVICE
Caring for our community

CareOregon®

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EASTERN OREGON
COORDINATED CARE
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WVCH
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September 29, 2016

Oregon Drug Use Review / Pharmacy and Therapeutics Committee

Hepatitis C Class Update:
HERC recommendations concerning
Sofosbuvir/velpatasvir and elbasvir/grazoprevir
Non-invasive assessment of fibrosis
Expand fibrosis treatment criteria to include F2

We strongly support inclusion of sofosbuvir/velpatasvir and elbasvir/grazoprevir in the OHP HCV treatment armamentarium. The former (SOF/VEL) provides at least comparable cure rates of GT 2 and 3 compared to currently approved regimens with better tolerance, generally shorter duration therapy and potential cost savings. Because it is "pangenotypic," with minimal side effects and high efficacy in cirrhotic patients, it offers the promise future safe use by primary care providers with out need for genotyping, fibrosis measurement or frequent lab monitoring. The later (EBR/GBR) provides comparable cure rates at potentially lower costs and has been responsible for markedly lower negotiated prices in the HCV market place.

Adoption of non-invasive testing for fibrosis markers is in keeping with current clinical practice and national guidelines. We support the guidance for coverage imaging tests (Transient elastography, ARFI and shear wave elastography, independent of manufacturer) and blood testing as proposed.

We are very supportive of the incremental step to include HCV patients with F2 fibrosis, as we recommended earlier in the year. This is congruent with the OHA 2017-2018 budget request application that proposes a policy option package for expansion for HCV treatment that includes F2 patients. The budget proposes $261,939,000 to fund treatment, which would treat ~ 3,300 patients at the current OHA treatment price of $79,000 per patients (including rebates, per OHA CFO). We estimate that his constitutes about ¼ of HCV patients in OHP with F2 – F4 fibrosis. In order for the OHP to obtain best prices of HCV drugs, as have other states and federal agencies, approaching 75% to 80% off, the state must proactively negotiate among the competing drug companies for all OHP patients as a pool. With the proposed budget, there is potential to treat 10,000 or more HCV patients in the 2017-2018 biennium, if best prices can be obtained.

We believe the essentially all HCV patients should be treated, as recommended the AASLD/ISDA guidance and the CMS Guidance to states (11/5/15). To accomplish this, the OHA should competitively engage all manufactures of safe and effective HCV treatments to obtain the best price. We support allowing primary care providers knowledgeable in HCV care to treat on there own in order to expand the

HCV provider network. We also support treating substance abuse as a separate medical issue to be managed independent of HCV treatment.

Sincerely,

Kent Benner MD, The Liver Clinic, The Oregon Clinic, GI East
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The HCV Advisory Group