Global Blood Therapeutics, Inc. OXBRYTA (voxelotor) Tablets or Tablets for Oral Suspension

Global Blood Therapeutics would like to thank you for the opportunity to provide comment on the current voxelotor criteria.

THE ASK: ***We would like the committee to consider removing the pain crisis/vaso-occlusive crisis (VOC) requirement from the policy to align with our most recent clinical trial data. (prior authorization criteria- question #8)***

- Current criteria require patients to have a history of **AT LEAST ONE** pain crisis in the last 12 months.
- The HOPE-Kids 1 trial did not require children to have a VOC in the previous 12 months to enroll in the study.[1]
    - 21 patients (46.7%) in the HOPE-Kids 1 trial did not have a VOC in the past year.
- The annualized incidence of VOCs was evaluated as a secondary endpoint for safety in the Phase 3 pivotal HOPE trial. The results of this analysis provided reassurance that voxelotor treatment could safely raise hemoglobin without causing a viscosity-related increase in the risk of VOCs.[2]
    - The HOPE study was not enriched nor powered to evaluate VOCs as an efficacy endpoint.
- Although VOCs are a common complication of sickle cell disease (SCD), one retrospective study of patients with SCD showed that 52.3% did not have any VOC episodes over a 12-month period.[3]
- The FDA labeled indication does not include a requirement for having a VOC(s) prior to initiating treatment with voxelotor.[4]
    - Voxelotor inhibits hemoglobin S polymerization, the root cause of sickle cell disease pathology.
    - Patients who suffer from anemia and hemolysis can still potentially benefit from voxelotor regardless of the number of baseline VOCs.

Thank you for your time and consideration.

References:

1. Estepp J, et al. Safety and Efficacy of Voxelotor in Pediatric Patients with Sickle Cell Disease Aged 4 - 11 Years: Results From the Phase 2a HOPE-KIDS 1 Study. Poster presented at: Annual Meeting of The European Hematology Association (EHA); June 9 – 17, 2021; Virtual
2. Vichinsky E, Hoppe CC, Ataga KI, et al. A Phase 3 Randomized Trial of Voxelotor in Sickle Cell Disease. *N Engl J Med* 2019;381(6):509-19.
3. Shah N, Bhor M, Xie L, Paulose J, Yuce H. Sickle cell disease complications: prevalence and resource utilization. *PLoS ONE*. 2019;14(7):e0214355. doi:10.1371journal.pone.0214355
4. Oxbryta [package insert]. South San Francisco, CA: Global Blood Therapeutics; Revised 01/2021.

Caring Ambassadors Program
Lorren Sandt, Executive Director
P.O. Box 1748
Oregon City, OR 97045

Public Comment
HCV Direct-Acting Antivirals Class Update and Treatment Guidelines

OSU Drug Use Research and Management Program
Oregon Drug Use Review / Pharmacy & Therapeutics Committee
April 7, 2022

The Caring Ambassadors Program is a national, nonprofit advocacy organization based in Oregon City, Oregon. We respectfully submit our written comment on the proposed update to the current Hepatitis C PDL class to treat the Hepatitis C Virus (HCV). We would like to recognize and thank you for the previous changes that have allowed us to increase access to care and cure for Oregonians living with hepatitis C.

We encourage the P&T Committee to support the removal of clinical prior authorization (PA) criteria for preferred HCV DAAs on the Oregon Health Plan FFS Preferred Drug List in treatment-naïve patients. Removing this barrier will keep Oregon in line with the national treatment guidelines and ensure equitable access to these lifesaving medications. Your vote today to remove the PA will help Oregon achieve elimination of hepatitis C as a public health crisis. Your vote will save lives.

Thank you for all your work, your time, and consideration.

Respectfully,

Lorren Sandt
Executive Director
Caring Ambassadors Program

Title: Arguments for dropping prior authorization requirements for HCV direct-acting agents

Author: Ann Thomas, MD, MPH
Public Health Physician, Acute and Communicable Disease Prevention
Oregon Health Authority
ann.r.thomas@dhsoha.state.or.us

From a public health standpoint, removing the prior authorization requirement for use of HCV direct-acting antiviral agents (DAAs) is an important step towards eliminating HCV in Oregon. Prior authorization requirements place a big administrative burden on providers; dropping the requirement will make it more feasible for primary care providers to care for patients with HCV.

Prior authorization requirements are also a barrier to initiating treatment at the first contact with Oregonians who are the hardest to reach—persons who inject drugs and those who are houseless, which are often co-occurring conditions. These vulnerable Oregonians represent a highly stigmatized and marginalized population, and they can be difficult to engage in treatment. Any steps we can take to streamline office procedures and reduce administrative hurdles will increase the numbers of people who can take advantage of these safe, easy to administer, and highly effective medications.

In Oregon and the US, we know that the prevalence of HCV is highest in baby boomers, and we have made great strides in Oregon in treating this age group since 2015, when direct acting antiviral medications became available. Based on some modeling results from an analysis conducted in 2019, Oregon was on target to reduce the prevalence of HCV by 90% by the year 2030.[1]

But we are facing a new wave of cases in young adults: the highest rates of acute HCV occur in people aged 20-29, and the rates of newly diagnosed cases of chronic HCV in persons under the age of 30 have also been climbing. Cases in young adults most commonly occur in people who are actively injecting drugs, and who are at the highest risk of transmitting the infection. Just as we did successfully with HIV, we have adopted the strategy of treatment as prevention, which aims at targeting treatment for those mostly likely to transmit the infection to others as an important component of our elimination strategy.[2,3]

And unlike baby boomers, where cases are more common in males, half of HCV cases in younger adults occur in women of child-bearing age. It follows then, that by treating more young women with HCV, we can also potentially decrease the rate of perinatal transmission in Oregon, which we know is rising.

Lastly, I would like to emphasize that we are not opening the floodgates. In 2019, based on All Payer All Claims data, just over 4,000 Oregonians initiated treatment for HCV. Modeling data suggest that we need to treat between 3,000 to 5,000 HCV patients a year between 2020 and 2030 to meet WHO goals for eliminating HCV (which requires 90% diagnosis of all HCV infections, 80% reduction in new infections, and 65% reduction in liver-related mortality).

These numbers are very feasible. We got to 4,000 by dropping restrictions based on sobriety and fibrosis scores without overwhelming providers and healthcare systems. Today's proposal to drop all prior authorization requirements will simply ease the administrative burden of treating patients who are at highest risk of spreading HCV.

So, if we can restore rates of treatment to pre-pandemic levels and focus more efforts on treating those who actively inject, HCV elimination is within reach. However, the success of our elimination campaign will hinge on our ability to prevent new cases, thus the importance of treatment as a prevention strategy.

References

1. Center for Disease Analysis Foundation. Public health impact of a population-based approach to HCV treatment in Oregon report. 2019, 1-20.
2. Zelenev A, Li J, Mazhnaya A, Basu S, Altice FL. Hepatitis C virus treatment as prevention in an extended network of people who inject drugs in the USA: a modelling study. The Lancet Infectious Diseases 2018;18:215-24.
3. Fraser H, Zibbell J, Hoerger T, et al. Scaling-up HCV prevention and treatment interventions in rural United States-model projections for tackling an increasing epidemic. Addiction 2018;113:173-82.

From: Barry L Schlansky <Barry.L.Schlansky@kp.org>
Sent: Friday, April 1, 2022 11:08:59 AM (UTC-08:00) Pacific Time (US & Canada)
To: Pharmacy Drug Information
Subject: Oregon P&T Committee written testimony for hepatitis C

To the Oregon P&T Committee:

I am a practicing hepatologist (liver specialist) in Portland, OR. I currently practice at Kaiser Permanente in Portland, and I have previously served as a faculty member at OHSU for a 5-year period. I am writing to strongly support the recommendation for removal of prior authorization for hepatitis C treatment for the Oregon Health Plan. I believe this action, if enacted, will offer major benefits to the health of Oregonians by removing a barrier to hepatitis C treatment access, which will help to further stem the rising tide of the hepatitis C epidemic, which has unfortunately worsened in the setting of increasing opiate use disorders related to the COVID-19 pandemic. I further support the recommendation to continue a prior authorization requirement for the more complicated subset of hepatitis C management involving treatment-experienced patients, non-preferred DAAs, and non-FDA approved indications.

Thank you for supporting hepatitis C care in Oregon. Please feel free to contact me with any questions or concerns. My completed Conflict of Interest form is attached.

Thank you,

Barry Schlansky, M.D., M.P.H.
Department of Gastroenterology & Hepatology
Kaiser Permanente Northwest
Portland, OR

From: Douglas Carr, MD
Sent: Wednesday, April 6, 2022 3:09:39 PM (UTC-08:00) Pacific Time (US & Canada)
To: Pharmacy Drug Information <osupharm.di@oregonstate.edu>
Subject: Written Testimony

Umpqua Health Alliance strongly opposes the proposal for removing prior authorization (PA) criteria and required case management for any OHP member for the treatment of Hepatitis C with direct acting anti-viral regimens.
This is a proposal based on virtuous sentiment, but lacks real world practicality.

The simplicity of therapy and treatment guidelines has fortunately expanded this management into the Primary Care arena and we have educated our clinics to prescribe these agents
Our experience in Douglas County is that the PA process does **not** create barriers to obtaining these drugs, but ensures successful completion of a course of therapy, which is the true goal.
The PA is the only practical way for health plans to initiate coordination and member coaching. For example, many UHA homeless members are provided motel accommodations to assist in completion of their course of therapy.
When a provider writes a prescription for the DAAV, the medications are not usually available for up to a week, as these are ordered and shipped from a specialty pharmacy, so the argument that removing this PA will provide immediate access is simply not true for most of the state.

Though the proposal applies only to FFS pharmacy, we all know that the CCOs will be held accountable to the same standard shortly.

We object that this vote was scheduled without bringing this topic to either QHOC, the OHA Pharmacy Director meeting, CCO Ops, or the CCO CEO meeting for input. We feel that this should be deferred to 2023 when the Risk Corridor contract has ended, which would allow for input from these groups about considerations on how best to operationalize this.

Sincerely,
F. Douglas Carr, MD

UMPQUA HEALTH
F. DOUGLAS CARR, MD | *Chief Medical Officer*

500 SE Cass St. Suite 101 | Roseburg, OR 97470
P: 541.464.4070 | F: **541.677.5881**
umpquahealth.com | **dcarr@umpquahealth.com**

LISA REYNOLDS, MD
STATE REPRESENTATIVE
District 36

HOUSE OF REPRESENTATIVES

Wednesday, April 6th, 2022

Dear Oregon Pharmacy and Therapeutics Committee,

I am writing today in support of removing prior authorization for direct-acting antiviral treatments for the Hepatitis C virus (HCV).

As you know, HCV is on the rise across the country, and Oregon has one of the highest infection rates - 95,000 individuals suffering from the virus. One of the main risk factors for contracting HCV is the use of intravenous drugs and sharing of needles. The increased prevalence of intravenous drug use, as a result of the opioid epidemic, is costing our communities dearly, particularly younger adults. Over the past few years, those under the age of 30 have been making up over half of the new HCV cases in the state. Of these individuals, more than half are unaware they have the virus, and 75-85% will develop chronic infections, leading to liver damage or even cirrhosis.

The new direct-acting antiviral treatments which became available a few years ago showed us a way out of this crisis. A 90-day treatment period for most individuals can completely stop the progression of the virus. However, in Oregon, these interventions are often not administered in time to prevent the development of chronic HCV. This is partly due to our system of requiring prior authorization from health insurers. While treatment for HCV may be costly, it can vastly improve the quality of life for individuals suffering from this virus and reduce the burden on our state.

Removing the need for prior authorization for HCV treatments is both cost-effective, and the right thing to do to protect the health of our communities.

I thank the Committee Members for their time and hope you will consider my recommendations as you make this determination.

Sincerely,

Representative Lisa Reynolds, MD

RACHEL PRUSAK
STATE REPRESENTATIVE
DISTRICT 37

April 4, 2022

Dear Oregon Pharmacy and Therapeutics Committee:

The opioid epidemic in Oregon has fueled viral Hepatitis C infections, and today approximately 48,700 Oregonians are living with Hepatitis C (HCV). Unfortunately, the actual number of infected individuals could be significantly higher, because it is estimated that 50 percent of infected individuals do not have symptoms and have not been diagnosed. In 2017, 518 Oregonians died from HCV related health conditions.

Over 66% of individuals who contracted HCV reported injection drug use, and this population does not readily seek medical attention due to stigma or access barriers. This means we must seize the opportunity to initiate treatment for HCV when we have a patient in our care. One essential way to do this is to remove prior authorization for HCV treatments.

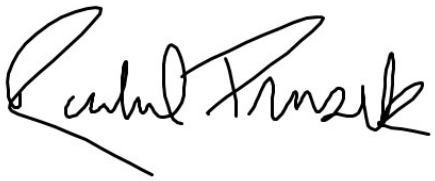
Removing prior authorization for every HCV infected patient will help Oregon meet our goal of eliminating health disparities. The incidence rates of HCV infections are highest among American Indian / Alaska Natives at three times that of whites, and Blacks and African Americans experience rates twice as high as whites. The rates of deaths from HCV are twice as high among American Indians / Alaska Natives, and average 79% higher for Blacks than among whites.

Today's treatment for HCV can cure most people in 8 to 12 weeks. Curing this disease early will prevent pain and suffering, death, and reduce health care costs by preventing more serious liver disease, as well as future infections. There are now 11 states that have removed prior authorization restrictions to HCV, including Washington, Louisiana, and New York; Oregon should join them.

I urge the P&T Committee to support the removal of PA for preferred HCV treatments, and help Oregon eliminate HCV.

Thank you for your service and consideration.

Sincerely,



Rachel Prusak, FNP
State Representative