**From:** Shawn Sills
**Sent:** Thursday, January 19, 2017 10:37:39 PM (UTC-08:00) Pacific Time (US & Canada)
**To:** Pharmacy Drug Information
**Subject:** Written Testimony

To whom it may concern,

The following is a letter of support to remove the need for prior authorization and to remove the barriers of access to Injectable Naltrexone (Vivitrol) and Buprenorphine for Oregon HealthPlan patients suffering from opiate use disorder.

My name is Shawn Sills, MD and I am one of a few physician in southern Oregon board certified in Addiction Medicine. I am the chief medical officer of the Addiction Recovery Center in Medford, OR and run an outpatient buprenorphine tapering clinic.

It is hard for me to continue to watch the repetitive failures for treating these patients because they do not have access to tools that we know are effective for greatly improving outcomes. When we detox patients, we see a near universal failure with inevitable relapse often quickly followed by death. These are our sons and our daughters and other loved ones. There is hardly a family in Oregon that is not directly or indirectly affected by this opioid epidemic.

In our area, because of the barriers in place, our OHP patients either go back to the streets or are directed to the Methadone clinic. Our Methadone clinic is booming and at full capacity. Recently, our neighboring community in Grants Pass opened its own Methadone clinic. It seems that currently the barriers for community physicians to treat patients with other forms of MAT such as buprenorphine and vivitrol mean patients have no other choice but heroin or methadone. And although our local methadone clinic does an excellent job, I wonder about the long term consequences of methadone maintenance that are rarely discussed. These include endocrine dysfunction resulting in hypogonadism, sexual and erectile dysfunction, fertility problems and advanced osteoporosis. Also, increased mental health problems with depression and anxiety, behavioral changes, GI dysfunction and constipation and obstruction, cardiac conduction delays, tooth decay, and of course respiratory depression. And I wonder if prolonged full agonist therapy causes permanent changes that decrease the ability to ever be opioid non dependent.

We need better options and Oregon should join other states like Washington who have in the face of this epidemic equipped physicians like myself to be proactive in turning the tide of opiate addiction.

I will share two success stories from my practice. These patients have commercial insurance and were able to get on Vivitrol. Patient 1 is a 22 year old male who was injured as a child and became a paraplegic. He was exposed to pain medicine as a child and in his teens moved to heroin addiction. For two years I treated him with buprenorphine but as doses were lowered he would develop cravings and relapse. Being sick of using heroin he decided against full agonist therapy with methadone and instead detoxed and was started on Vivitrol. He has been sober for over 6 months. He is a different kid.

Patient 2 is a middle age female that I first encountered in my pain clinic. She was discharge when she began abusing her medication. I saw little hope for her ever getting clean. But, she too was sick of living the addict lifestyle. She went to detox and was placed on Vivitrol. She is also almost 6 months sober. Her marriage is not the mends and she is present for her children.

Both of these patients I would have given almost zero chance of success. But having access to Vivitrol has made all the difference for them both.

I hope this committee recommends the removal of prior authorizations for these life preserving medications. To me, the financial savings are obvious.

Please feel free to reach out to me if you would like more information on the evidence based literature supporting these two modalities.

Best regards,

Shawn Sills, MD

**From:** Tim Murphy
**Sent:** Thursday, January 19, 2017 3:25:58 PM (UTC-08:00) Pacific Time (US & Canada)
**To:** Pharmacy Drug Information
**Subject:** Written Testimony

I plan on attending your hearing on Thursday January 26th to provide testimony in favor of removing the current prior authorization criteria for the use of Vivitrol and Buprenorphine. It is vital to so many Oregonian's struggling with symptoms of addiction to obtain treatment and the supervised use of these medications make accessing and keeping fidelity to treatment goals much easier. Since Bridgeway began providing these medications we have seen an increase in requests for help and support. The medicines are often the difference between being successful in treatment and failing treatment.
By removing the prior authorization process we can more readily provide treatment when the patient is in both need and readiness for help.

Thank you for considering my request for removing the prior authorization restriction.

Sincerely,

Tim Murphy
Bridgeway Recovery Services
Chief Executive Officer
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Bridgeway
Freedom Through Recovery

Oregon Business 100 Best NONPROFITS to work for in Oregon 2015

**From:** Debora Stout
**Sent:** Saturday, January 14, 2017 11:19:33 AM (UTC-08:00) Pacific Time (US & Canada)
**To:** Pharmacy Drug Information
**Subject:** Written Testimony

To Whom It May Concern,

I am a psychiatric mental health nurse practitioner in Astoria OR. I contract with the agency that provides mental health and chemical dependency to the participants in Clatsop County Drug Court. I started trying to prescribe Vivitrol in March of 2015. The prior authorization process is cumbersome and at best delays care for patients. At worst, it prevents patients from receiving appropriate care, and leads to relapse, morbidity and mortality.

The current requirement that patients must first fail methadone, suboxone and oral naltrexone prior to begin able to receive Vivitrol is very problematic. Most of the opiate addicts who are in drug court have an extensive history of abusing opiates, and have abused every type of available opiate including in most cases suboxone and methadone. This makes it very difficult to consider recommending these medications as the risk of diversion, abuse and subsequent relapse is high.

The original guidelines indicated that oral naltrexone was only a prerequisite to Vivitrol for alcohol abuse, for the very good reason that it is difficult or impossible for most heroin addicts to comply with the daily oral treatment regimen. I have not seen oral naltrexone to be effective for any of the addicts in our drug court, nor do I find much documentation in the literature reporting success of oral therapy in opiate addicts, especially IV heroin addicts. This requirement in the prior authorization puts the provider in the hopelessly unacceptable position of being expected to prescribe a treatment with little chance of success, so that if (when) the client does relapse they will qualify for a trial of an agent that is much more likely to actually work. Failure on oral naltrexone means relapse. And relapse at best means increased risk, vulnerability and suffering. Unfortunately, relapse also can result in overdose and death. Requiring failure on oral naltrexone prior to authorization to obtain Vivitrol is basically a prescription for relapse, and relapse is potentially fatal.

The majority of heroin addicts that I have met through the Clatsop County Drug Court began abusing opiates before the age of 18 and a significant percentage were first exposed to opiates by a medical provider following an injury or surgery. It seems both ironic and very wrong that there are minimal barriers to the prescriptions of what for some clients probably was the gateway into the eventual addiction, while at the same time there are what can be insurmountable barriers to accessing Vivitrol.

As most who work with heroin addicts are keenly aware, this is a very difficult addiction and our clients struggle mightily to get and to stay clean. It is critically important to be able to provide services, including Vivitrol, when the client is ready and motivated. The prior authorization process pretty much guarantees that for many this crucial window of opportunity will be missed.

Four clients of the Clatsop County Drug Court immediately come to mind when I think about the risks inherent in adding any additional delays to starting Vivitrol for heroin addiction. Each were appropriate candidates for Vivitrol therapy and very motivated for this treatment. Three of these individuals had dropped out of treatment and were on abscond status with respect to their probation by the time I was able to obtain the prior authorization. I have no way of knowing what the outcomes might have been if each of these clients had actually received a chance at Vivitrol therapy, but it seems very wrong to me that this treatment was ultimately unavailable to clients who were appropriate and may well have benefited. A fourth client suffered a fatal overdose in October 2015. There were several confounding factors that lead to a delay in his ability to obtain the Vivitrol injection, but I beleive that the delay inherent in the prior authorization process certainly was a factor. What ever else may have gone on for this young man, I seriously doubt that he would have overdosed on heroin when he did if he had been able to obtain the Vivitrol injection in a more timely manner.

I was heartened to hear that Medicaid in both Washington and Idaho have removed the prior authorization for Vivitrol, and hopeful that Oregon will see fit to follow suit. We can not afford to lose any more people to this epidemic.

Respectfully,

Debora Stout, PMHNP
Psychiatric Mental Health Nurse Practitioner

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**From:** Jim Shames
**Sent:** Tuesday, January 10, 2017 12:16:27 PM (UTC-08:00) Pacific Time (US & Canada)
**To:** Pharmacy Drug Information
**Subject:** Written Testimony

Hello; I am a buprenorphine prescribing physician working at a federally supervised methadone/buprenorphine treatment facility in Medford Oregon. I have one of the largest number of buprenorphine patient volumes in the State, since I have been providing this service for many years, and I have no "cap" on numbers, as a private practice doctor might. I want to briefly explain my experience with buprenorphine PAs since I have worked with them and without them.

At first the CCOs we worked with required PAs prior to paying for buprenorphine. In my world, where patients were ready for treatment "NOW," in withdrawal and ready to bolt and return to heroin if there were a delay in response, such PAs made no sense. In fact, in almost every case, when presented with a delay, patients either opted for methadone (a more dangerous medication alternative) or to return to the "street." In short, PAs for buprenorphine did not work, and led to riskier behaviors on the part of my patients.

I was fortunate to have understanding Medical Directors at our local CCOs and they agreed to allow me to prescribe buprenorphine at first visit, with the proviso that follow up paperwork and treatment modalities be fulfilled at a later date. That has worked very well over the years. We all know that buprenorphine is safer the methadone for most patients, and obviously safer than illicit opioids for all.

I strongly recommend that buprenorphine be prescribed initially without a prior authorization. Follow up documentation, and adherence to guidelines are fine, but they shouldn't stop initiation of the drug for even an hour. The consequences of delay could be fatal.

Jim Shames MD

**From:** Jill Franskousky
**Sent:** Tuesday, January 10, 2017 2:42:03 PM (UTC-08:00) Pacific Time (US & Canada)
**To:** Pharmacy Drug Information
**Subject:** Written Testimony - Vivitrol Treatment

To Whom it May Concern

Integra Health is an opioid addiction treatment practice with clinics located in Tigard, OR and Bellevue, WA. We've been treating patients for 10 years and provide both medical and counseling services.

We are committed to helping our patients become and remain sober and welcome the opportunity to remove barriers to treatment wherever we see them. To that end, I'd like to provide the following testimony for your consideration regarding Vivitrol which is one of the medications that we prescribe in our clinics.

Currently, the pre-authorization process necessary for this medication causes needless delays and negative impact on a vulnerable patient population. If the pre-auth process was eliminated or streamlined, it would have immediate and meaningful positive effects for many in our community. Below are some comments in support of this perspective.

- The current rule for pre-authorization for Vivitrol is that a candidate (patient) must have failed opioid replacement therapy twice before becoming eligible for this medication. Where to begin? The Hippocratic oath? Patients risk relapse and worse as they "fail their way" to becoming a candidate for this medication. I wonder how many other therapeutic alternatives face this same approval hurdle. It doesn't make sense on any level. Physicians should have the ability to prescribe the appropriate treatment for patients at the time when treatment is needed....not at a later point in time after the disease of addiction has taken a further toll on the health and well-being of an already vulnerable patient. Vivitrol is a safe treatment option and yet this medication seems to be held to a different pre-authorizaton standard than its alternatives. In fact, it is safer from the perspective of potential diversion risk.

- Once a patient is on the medication, pre-authorization is still required periodically. This frequently takes two weeks and the process can result in delays that again put the patient at risk of running out of medication.

I'm glad to be able to send this feedback for your consideration. I hope the perspective of providers plays a role in the decision making process for pre-authorizations. We take our responsibility to our patients seriously and we want to make all appropriate therapeutic alternatives efficiently available to them on their road to recovery.

Thanks for the opportunity to weigh in on this important matter.

Kind Regards,

Jill G. Franskousky | CEO

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**From:** Daniel Sudakin
**Sent:** Friday, January 20, 2017 1:27:48 PM (UTC-08:00) Pacific Time (US & Canada)
**To:** Pharmacy Drug Information
**Subject:** Written Testimony for P and T Committee meeting 1/26/17

To the Committee

I am a board certified addiction medicine physician practicing in Portland. I have been providing medication assisted treatment for patients with opioid and alcohol use disorders for several years. During that time, I have gained a lot of experience in the use of FDA-approved medications in the treatment of opioid use disorder (including buprenorphine and extended release naltrexone/Vivitrol) and alcohol use disorders (naltrexone and extended release naltrexone/Vivitrol).

In my experience, the vast majority of patients receive substantial benefit in their quality of life from the appropriate use of these medication assisted treatments. These medications help people regain their function, and enable them to do the difficult work of getting back to things that are important in life, including family, work, and getting out of the criminal justice system.

If there has been one consistent barrier that I have encountered in prescribing these medications, it is the prior authorization hurdles that providers encounter in getting patients access to treatment in a timely and reasonable manner. While I completely understand the rationale of confirming the diagnosis and medical necessity for appropriate use of these medications, there have been too many times that my requests for prior authorization have been denied or delayed. The reasons for denial or delay typically have nothing to do with the documentation provided or diagnosis codes rendered by me. The denials sometimes arise from requirements that a patient need to have tried and failed other treatments. I have also had requests denied or delayed without any clear reason. The time that it takes for a physician and their staff to try to follow-up on these prior authorizations can be substantial, and adversely impact patient care.

When a patient is ready for change and is a good candidate for medication assisted treatment with buprenorphine or naltrexone, time is of the essence. When treatment is delayed or denied, patients can fall through the cracks, relapse, and can experience injury, overdose, or death. I would support any effort that would streamline the prior authorization process for these medications, so that providers can give the care they need in a timely manner, and patients can receive the benefits of effective treatments for their serious substance use disorder.

Thank you for considering these comments,

Sincerely,

Daniel Sudakin, MD, MPH, LLC
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**From:** Martin Klos MD
**Sent:** Thursday, January 12, 2017 3:02:33 PM (UTC-08:00) Pacific Time (US & Canada)
**To:** Pharmacy Drug Information
**Subject:** Written testimony on Prior auth for addiction meds
**Date:** January 12, 2017
**Re:** Prior Authorization for addiction treatment drugs

Dear Committee Members:

I am board certified in addiction medicine and treat addiction problems as a physician in Oregon. I am also the current president of the Oregon Society of Addiction Medicine. We have a severe shortage of trained doctors in Oregon willing and/or able to treat opiate addiction. At the same time, we have one of the country's highest death rates per capita for opiate overdose. Ithas been well proven addiction is a mental disease that is a combination of genetic inheritance and exposure. Heroin is very cheap in Oregon right now and exposure is easy for our youth to get. Despite the state cutting back on the pain treatment for pain patients, the opiate medications are also still very easy to obtain through the internet and other sources.

Yet almost daily, I encounter non-medical obstructions that insurance companies, especially the Oregon Health Plan, place in the way of my patients obtaining needed medications for their treatment. People who do not treat and have little to no experience with addiction are deciding whether my patients can receive their medications, what dose they need and what labs I need to order (at the patient's expense). My patients often cannot afford their medication without the insurance helping to pay for it, and they often then will return to the use of heroin. Relapse after treatment starts is a deadly phenomenon with a higher percentage of death from overdose then for the person who never started treatment. Insurance companies are also putting limits on how long patients can be treated with their lifesaving medications. This is despite the known life-long duration of the disease of addiction. People are dying and the only thing I can assume is that the insurance companies, including our local OHP providers, do not care enough to read the statistics and understand the disease.

Death is often the result of not paying for good treatment. However, perhaps more important to the OHP population is the cost of the false ideas. A patient who relapses is more at risk of emergency room visits, hepatitis B, C, and HIV infections and other medical results of their disease. This adds tremendously to the cost of medical care in our state. Please do the best service you can to this underserved population in our state and remove the restrictions on the use of Vivitrol, Naltrexone, and Buprenorphine products that have been put in place artificially by the insurance companies and the Oregon Health Plan.

Sincerely,

Martin M. Klos MD MBA
President Oregon Society of Addiction Medicine
Diplomate American Board of Addiction Medicine
Fellow American Society of addiction Medicine