Issue Brief: Pennsylvania Medicaid Pre-authorization Requirements for Prescription of Buprenorphine/Naloxone Combination Therapy for Opioid Use Disorder

The College of Physicians of Philadelphia, Section on Public Health and Preventive Medicine

January 2018

Combination buprenorphine/naloxone medications are a safe and effective outpatient treatment for opioid use disorder and, unlike methadone, can be prescribed by primary care, emergency medicine, and other physicians who are not addiction specialists.[i,ii,iii] When taken as prescribed, buprenorphine, a partial μ-opioid agonist, reduces craving for opioids without producing the "high" associated with heroin or commonly misused pharmaceutical opioids.[iv] A well-established and growing body of evidence and experience demonstrates that buprenorphine[1] can be used successfully on a long-term basis by many patients with opioid use disorder.[1] Unfortunately, current Pennsylvania Medicaid pre-authorization procedures for medication assisted treatment (MAT) with buprenorphine for opioid use disorder introduce significant barriers that constrain access for our patients. This includes a requirement that patients are enrolled in, or are in the process of being placed into, a licensed substance abuse or behavioral therapy program (see Appendix).[v] Although pharmacists in Pennsylvania are permitted to dispense a 5-day supply of a prescribed medication without prior authorization if "the recipient has an immediate need for the medication,"[vi] this option has not solved problems resulting from pre-authorization requirements for buprenorphine.

[1] For brevity, the term "buprenorphine" will be used to refer to buprenorphine/naloxone combination medications.

A real-life case in point involving the patient of one of our physician members illustrates the potentially fatal consequences of these requirements.

> Eight years ago, Ms. F. was diagnosed with opioid use disorder, prescribed buprenorphine, and subsequently continued treatment without relapsing to illicit opioid use. During this time, she was gainfully employed, and her employer-sponsored health insurance covered her treatment. Due to changes at her workplace, Ms. F. was recently laid-off. She immediately applied for and promptly obtained Pennsylvania Medicaid coverage. Unlike her prior private insurance, her Medicaid policy required pre-authorization to obtain buprenorphine, and she experienced difficulty arranging the required behavioral therapy. While waiting, she ran out of buprenorphine and relapsed. She went to her old neighborhood and bought heroin. The heroin contained fentanyl, and she overdosed and died.

This was a tragic and preventable incident. While patients suffering from opioid use disorder face multiple obstacles accessing treatment, including procedural barriers to obtaining buprenorphine, overdose fatalities continue to occur in Philadelphia and throughout Pennsylvania. In 2016, 907 people died from overdoses in Philadelphia, with over 80% of deaths involving opioids.[vii] For 2017, the Philadelphia Department of Public Health has projected a 30% increase in overdose deaths.[viii] Statewide, there were 4,642 overdose deaths in Pennsylvania in 2016, a 37% increase from the prior year.[ix]

Federal regulations do not mandate that states impose these pre-authorization requirements for buprenorphine, and the American Medical Association has stated that, "There is no medical, policy or other reason for payers to use prior authorization for MAT."[x] The Pennsylvania pre-authorization requirements, however well-intentioned to control costs or promote use of behavioral therapies, are no longer warranted in the face of our state's opioid crisis. The cost of buprenorphine is comparable to costs of medications that do not require pre-authorization and are used on a long-term basis for chronic conditions like asthma or diabetes. Although behavioral therapy might be useful for some patients with opioid use disorder, evidence demonstrating effectiveness of behavioral therapy in addition to medication-assisted therapy is

lacking relative to evidence demonstrating effectiveness of buprenorphine alone.[i] Nonetheless, Pennsylvania Medicaid patients are at risk of being denied coverage for buprenorphine if they miss a behavioral therapy session. Advances in scientific understanding of substance use disorder as a medical condition, not a personal choice, has informed medical approaches to treatment, but constraints on physicians and patients surrounding buprenorphine prescription mark this treatment as different from treatments for other chronic diseases. Moreover, failure to treat opioid use disorder can lead to injection of heroin and other opioids, with accompanying risks from shared injection equipment for exposure to HIV, hepatitis B and C, and serious bacterial infections, which themselves are life-threatening and incur substantial health care costs.

In June 2016, the Governor of New York signed into law comprehensive legislation aimed at combatting the opioid crisis, including a provision that ended Medicaid pre-authorization requirements for MAT in his state.[xi] Later that year, the New York state Attorney General took legal actions against private insurers' pre-authorization requirements for MAT on the grounds that they violated federal laws that require parity in insurance coverage for mental health/substance use disorders and medical/surgical conditions,[xii] a step the American Medical Association endorsed and urged other states to follow.[x,xiii] As a result, other private plans have dropped pre-authorization requirements, and other states have taken or initiated similar actions.[xiv,xv]

In light of this information and Governor Wolf's commitment to reducing administrative barriers to addressing the opioid crisis in his declaration of "a statewide disaster emergency,"[xvi] we believe it appropriate to reassess our state's Medicaid pre-authorization requirements for the prescription of buprenorphine in treating opioid use disorder.

Appendix. Pennsylvania Medicaid prior authorization form for opiate dependence treatments.[xvii]

pennsylvania
DEPARTMENT OF HUMAN SERVICES

Office of Medical Assistance Programs
Fee-for-Service, Pharmacy Division
Phone 1-800-537-8862 Fax 1-866-327-0191

OPIATE DEPENDENCE TREATMENTS PRIOR AUTHORIZATION FORM

Prior authorization guidelines and Quantity Limits/Daily Dose Limits are accessible at http://www.dhs.pa.gov/provider/pharmacyservices/index.htm.

For Vivitrol requests, use Vivitrol Fax Form. *** For Probuphine requests, use Probuphine Fax Form. ***

PRIOR AUTHORIZATION INFORMATION		PRESCRIBER INFORMATION	
☐New request ☐Renewal request	total # pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		State license #:	
Facility contact/phone:		NPI:	MA Provider ID#:
RECIPIENT INFORMATION		Street address:	
Recipient Name:		Suite #:	City/state/zip:
Recipient ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Preferred medication requested: ☐buprenorphine SL tablet ☐Suboxone SL film		**Non-preferred medication requested:** ☐Bunavail buccal film ☐buprenorphine/naloxone SL tablet		☐Zubsolv SL tablet ☐_____
Strength:	Directions:	Qty:	Requested duration:	Prescriber's DATA 2000 waiver DEA number:

Diagnosis (*submit documentation*):		Dx code (*required*):
1. Is the prescriber enrolled in the Pennsylvania Medical Assistance (MA) Program?		☐Yes ☐No
2. Is the MA Recipient, or any other person, being billed any amount (above the standard MA copay) for the Recipient's office visits?	☐Yes ☐No	***Prescriber signature (required):*** _____
3. Is the Recipient taking a benzodiazepine? *Submit Recipient's current medication list.*	☐Yes – list: _____	☐No
4. *Submit documentation* of results of a recent UDS for licit & illicit drugs of abuse (including buprenorphine, norbuprenorphine, oxycodone, fentanyl, carisoprodol, and tramadol).		
5. Does the request exceed the daily dose limit of 16 mg buprenorphine per day?	☐Yes – *Submit documentation supporting requested dose.* ☐No	
6. Did the prescriber or prescriber's delegate search the PDMP to review the Recipient's controlled substance prescription history before issuing this prescription for the requested medication?	☐Yes ☐No	*Submit documentation.*
7. *If the Recipient has been **taking an oral buprenorphine agent for > 12 months***, has a clinical assessment of treatment effectiveness and appropriate dosage been performed?	☐Yes – *Submit documentation.* ☐No or N/A	
8. ***For non-preferred requests***: Does the Recipient have a history of trial and failure, contraindication, or intolerance of the preferred oral Opiate Dependence Treatments listed above?	☐Yes ☐No	*Submit documentation for all agents tried.*

INITIAL requests

Check all of the following that apply to the Recipient and ***submit documentation for each item checked.***

☐has documentation of a history that supports the diagnosis of Opioid Use Disorder based on Diagnostic & Statistical Manual (DSM) criteria AND one of the following:
- ☐initial UDS that supports an opioid use disorder diagnosis (including testing for substances of abuse)
- ☐active withdrawal documented by a Clinical Opiate Withdrawal Scale (COWS) score of ≥ 9 at treatment initiation
- ☐history of opioid use disorder with cravings

☐has documentation of a signed consent form authorizing release of Recipient's medical information as it relates to this request
☐has an initial or scheduled evaluation by a licensed D&A provider or Single County Authority (SCA) to determine level of care
☐is participating in, or has been referred to, a licensed D&A program as recommended in the initial evaluation by D&A provider or the SCA
☐has documentation of a mental health screening
☐if diagnosed with a co-occurring mental health disorder, is receiving, or has been referred for, treatment

RENEWAL requests

Check all of the following that apply to the Recipient and ***submit documentation for each item checked.***

☐has a documented history in the medical record of abstinence from alcohol
☐is participating in, or has successfully completed, a licensed D&A program at the recommended level of care
☐if successfully completed the licensed program, is participating in a substance abuse or behavioral health counseling or treatment program or an addictions recovery program
☐if diagnosed with a co-occurring mental health disorder, is receiving, or has been referred for, treatment

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION TO DHS – PHARMACY DIVISION

Prescriber Signature:	**Date:**

Confidentiality Notice: The documents accompanying this telecopy may contain confidential information belonging to the sender. The information is intended only for the use of the individual named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any telecopy is strictly prohibited.

Form effective 12/21/17

References

[i] Dunlap B, Cifu AS. Clinical Management of Opioid Use. *JAMA* 2016;316(3):338-339.

[ii] D'Onofrio G, O'Connor PG, Pantalon MV. Emergency department–initiated buprenorphine/naloxone treatment for opioid dependence, a randomized clinical trial. *JAMA* 2015;313(16):1636-1644.

[iii] Substance Abuse and Mental Health Services Administration. Quick Guide for Physicians Based on TIP 40, Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. URL: https://store.samhsa.gov/shin/content/SMA05-4003/SMA05-4003.pdf.

[iv] Greenwald MK, Johanson C, Moody DE, *et al*. Effects of buprenorphine maintenance dose on μ-opioid receptor availability, plasma concentrations, and antagonist blockade in heroin-dependent volunteers. *Neuropsychopharmacology* 2003;28:2000–2009. doi:10.1038/sj.npp.1300251. URL: https://www.nature.com/articles/1300251.

[v] Pennsylvania Department of Drug and Alcohol Programs. Treatment Manual, July 1, 2015—June 30, 2020, revised January 2016, Section 7.04, Medication Assisted Treatment (MAT), URL: http://www.ddap.pa.gov/Manuals/Treatment%20Manual.pdf.

[vi] Pennsylvania Department of Human Resources. Pharmacy Prior Authorization General Requirements, URL: http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/.

[vii] Philadelphia Department of Public Health. 2016 Overdoses from Opioids in Philadelphia. CHART 2017;2(7):1-3.

[viii] Task Force to Combat the Opioid Epidemic in Philadelphia. Status Report to the Mayor's Drug and Alcohol Executive Commission, December 13, 2017. URL: http://dbhids.org/wp-content/uploads/2017/12/OTF_StatusReport_December2017.pdf.

[ix] Drug Enforcement Administration Philadelphia Division and the University of Pittsburgh. Analysis of Overdose Deaths in Pennsylvania, 2016 (Unclassified). DEA-PHL-DIR-034-17, issued July 2017. URL: https://www.overdosefreepa.pitt.edu/wp-content/uploads/2017/07/DEA-Analysis-of-Overdose-Deaths-in-Pennsylvania-2016.pd_-1.pdf.

[x] Madara JL. Letter from the CEO of the American Medical Association t to the National Association of Attorneys General. February 3, 2017. URL: https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FAMA-Letter-re-AG-SChneiderman-MAT-FINAL.pdf.

[xi] Office of the Governor of New York. Governor Cuomo Signs Legislation to Combat the Heroin and Opioid Crisis, June 22, 2016. URL: https://www.governor.ny.gov/news/governor-cuomo-signs-legislation-combat-heroin-and-opioid-crisis.

[xii] New York State Office of the Attorney General. A.G. Schneiderman Announces National Settlement With Cigna To Discontinue Pre-Authorization For Opioid Addiction Treatment Drugs, October 21, 2016, URL: https://ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-cigna-discontinue-pre-authorization.

[xiii] Parks T. AGs called on to help stop prior authorization for MAT. AMA News, February 8, 2017, URL: https://wire.ama-assn.org/ama-news/ags-called-help-stop-prior-authorization-mat

[xiv] New York State Office of the Attorney General. A.G. Schneiderman Announces National Settlement With Anthem To Discontinue Pre-Authorization For Opioid Addiction Treatment Drugs, January 19, 2017, URL: https://ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-anthem-discontinue-pre-authorization.

[xv] Luthra S. Facing Pressure, Insurance Plans Loosen Rules For Covering Addiction Treatment. *Kaiser Health News*, February 21, 2017. URL: https://khn.org/news/facing-pressure-insurance-plans-loosen-rules-for-covering-addiction-treatment/.

[xvi] State of Pennsylvania. Governor Wolf Declares Heroin and Opioid Epidemic a Statewide Disaster Emergency (Press Release, Public Health, Substance Use Disorder), January 10, 2018, URL: https://www.governor.pa.gov/governor-wolf-declares-heroin-and-opioid-epidemic-a-statewide-disaster-emergency/.

[xvii] Pennsylvania Department of Human Resources, Opiate Dependence Treatments Prior Authorization Form, December 21, 2017, URL: http://www.dhs.pa.gov/cs/groups/webcontent/documents/form/c_092081.pdf.