State of Wisconsin
Department of Health Services
Tony Evers, Governor
Andrea Palm, Secretary

June 18, 2019

The Honorable Patrick Testin
Chair, Senate Committee on Health and Human Services
Room 131 South
State Capitol
PO Box 7882
Madison, WI 53707-7882

The Honorable Joe Sanfelippo
Chair, Assembly Committee on Health
Room 306 North
State Capitol
PO Box 8953
Madison, WI 53708

Dear Senator Testin and Representative Sanfelippo:

2017 Wisconsin Act 262 requires the Department of Health Services (DHS) to review its prior authorization policy on buprenorphine-containing products provided to medical assistance program recipients and submit a report. DHS is not required to submit the report after the date the prior authorization requirement for use of buprenorphine-containing products by medical assistance program recipients is eliminated for all appropriate populations.

The most recent review finds Wisconsin Medicaid's Preferred Drug List is in line with prescribing patterns across the state, as over 95 percent of prescriptions filled for buprenorphine-containing products are for listed drugs that no longer require prior authorization. The analysis also finds retaining a prior authorization requirement for nonpreferred buprenorphine-containing products does not create an undue barrier to access for Wisconsin Medicaid members since the overwhelming majority of claims are for preferred buprenorphine-containing products. The remaining drugs are approved via an expedited process.

The full report is attached.

Sincerely,

Andrea Palm-designee
Secretary

Wisconsin Medicaid Prior Authorization Policy
for Buprenorphine-Containing Products for Medication-Assisted Treatment
June 1, 2019

Overview

This report meets the requirements of the two directives regarding prior authorization for buprenorphine-containing drugs for Wisconsin Medicaid members as required by 2018 Executive Order 273 and 2017 Wisconsin Act 262.

2018 Executive Order 273 requires the Department of Health Services (DHS) to review whether to require prior authorization for buprenorphine treatment combination drugs for BadgerCare enrollees other than pregnant women.

2017 Wisconsin Act 262 requires DHS to review its prior authorization policy on buprenorphine-containing products provided to medical assistance recipients.

This analysis finds removing preferred buprenorphine-containing products from the prior authorization (PA) process was an appropriate action. It further finds retaining the specialized PA process for non-preferred products does not create an undue barrier to access medication-assisted treatment (MAT) while facilitating reduced risk for abuse.

Current Coverage Policy

Wisconsin Medicaid currently covers all available medication options used to treat opioid use disorder, including naltrexone, methadone, and buprenorphine-containing products.

Naltrexone and Methadone

Naltrexone and methadone for opioid use disorder are unrestricted and do not require prior authorization (PA). The risk for abuse of these drugs is very low since both products are administered under the supervision of a licensed provider.

Buprenorphine-Containing Drugs

In contrast, buprenorphine-containing drugs are dispensed at the pharmacy to the patient, which creates an inherently higher risk of diversion and/or misuse. The lone exception is for Sublocade, a provider-administered medication. Therefore, restrictions through PA have been required for some buprenorphine-containing drugs.

As of July 1, 2018, PA for *preferred* buprenorphine-containing products has been removed in response to the current opioid epidemic and the concern that PA for MAT products may cause an unnecessary delay in initiating treatment. It is widely recognized that the window of time to effectively treat opioid addiction is narrow. The longer the delay in treatment, the more likely an individual is to change their mind about pursuing treatment or to relapse if they start experiencing symptoms of withdrawal. Wisconsin Medicaid concluded the benefits of easing prescribing restrictions outweighed the risks of diversion or misuse for preferred buprenorphine-containing products. This is consistent with many commercial insurance companies who have also dropped the PA requirement for privately insured patients. Access to methadone and naltrexone continues to be unrestricted for the same reason.

Despite the benefits of easing prescribing restrictions for preferred buprenorphine-containing product noted above, Wisconsin Medicaid continues to retain PA for *non-preferred* buprenorphine-containing products. While Medicaid must pay for nearly all drugs under federal law, states are allowed to manage their pharmacy costs by placing drugs they consider to work the best and are the most affordable on a preferred drug list (PDL). Drugs listed on the PDL can often be obtained without PA to allow for easier access and to support value-based purchasing as the ability to leverage the manufacturer for better pricing remains intact.

In April 2018, Sublocade, a provider-administered, buprenorphine extended-release product and recently approved by the FDA, was added to the PDL as a non-preferred product. PA is required for Sublocade since it is a provider-administered medication.

Coverage policy for the buprenorphine containing class, as indicated in the chart below, includes a preferred product for each patient, self-administered dosage forms—film and tab. The non-preferred film and tab products are substitutes, meaning they are clinically interchangeable with the preferred drugs. However, these non-preferred products are considered not to be cost effective to the Wisconsin Medicaid program and, therefore, do not achieve preferred status.

Data provided in the previous report separated buprenorphine/naloxone products from buprenorphine-only products for the sake of comparison. However, since new products for the treatment of opioid use disorder that may be outside of these two classes of drugs are constantly coming to market, this report and subsequent reports will show claim totals and percentages for the full class of products in order to capture all new drugs.

Three quarters of data are provided in this report, including updated data from the third quarter of 2018 as well as data from the fourth quarter of 2018 and first quarter of 2019.

Data from the past three quarters after PA was removed for preferred buprenorphine-containing products on July 1, 2018, indicates that 94-96% of prescriptions filled for buprenorphine-containing products are for the *preferred* variety, for which PA is no longer required (see quarterly charts below).

Opioid Dependency Drugs Containing Buprenorphine Claims Data
July 1 – September 30, 2018

Drug Class	Drug Name	Dosage Form	PDL status	Prior Auth.	Diagnosis Restriction	Number of Claims	% of Claims
Buprenorphine/ Naloxone	Suboxone	Film	Preferred	NONE	Opioid Dependency	19,435	92.94%
	Zubsolv	Tab	Preferred	NONE	Opioid Dependency	293	1.40%
	Bunavail	Film	Non-preferred	PA required	Opioid Dependency	8	0.04%
	Buprenorphine-Naloxone	Tab	Non-preferred	PA required	Opioid Dependency	4	0.02%
Buprenorphine only	Buprenorphine	Tab	Non-preferred	PA required	Opioid Dependency for pregnant women	1,134	5.42%
Buprenorphine extended release	Sublocade	Provider Administered Injection	Non-preferred	Provider Administered PA required	Opioid Dependency	38	0.18%
					Total	**20,912**	**100%**

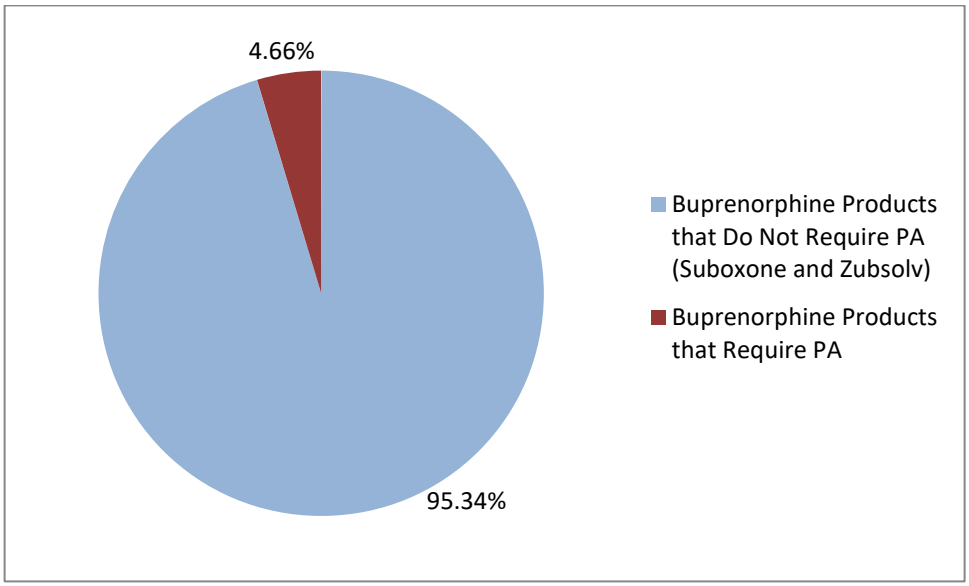
Opioid Dependency Drugs Containing Buprenorphine Claims Data
October 1 – December 31, 2018

Drug Class	Drug Name	Dosage Form	PDL status	Prior Auth.	Diagnosis Restriction	Number of Claims	% of Claims
Buprenorphine/ Naloxone	Suboxone	Film	Preferred	NONE	Opioid Dependency	23,103	92.08%
	Zubsolv	Tab	Preferred	NONE	Opioid Dependency	930	3.71%
	Bunavail	Film	Non-preferred	PA required	Opioid Dependency	6	0.02%
	Buprenorphine-Naloxone	Tab	Non-preferred	PA required	Opioid Dependency	5	0.02%
Buprenorphine only	Buprenorphine	Tab	Non-preferred	PA required	Opioid Dependency for pregnant women	951	3.79%
Buprenorphine extended release	Sublocade	Provider Administered Injection	Non-preferred	Provider Administered PA required	Opioid Dependency	94	0.37%
					Total	**25,089**	**100%**

Opioid Dependency Drugs Containing Buprenorphine Claims Data
January 1 – March 31, 2019

Drug Class	Drug Name	Dosage Form	PDL status	Prior Auth.	Diagnosis Restriction	Number of Claims	% of Claims
Buprenorphine/ Naloxone	Suboxone	Film	Preferred	NONE	Opioid Dependency	23,299	91.19%
	Zubsolv	Tab	Preferred	NONE	Opioid Dependency	1,158	4.53%
	Bunavail	Film	Non-preferred	PA required	Opioid Dependency	6	0.02%
	Buprenorphine-Naloxone	Tab	Non-preferred	PA required	Opioid Dependency	13	0.05%
Buprenorphine only	Buprenorphine	Tab	Non-preferred	PA required	Opioid Dependency for pregnant women	970	3.80%
Buprenorphine extended release	Sublocade	Provider Administered Injection	Non-preferred	Provider Administered PA required	Opioid Dependency	105	0.41%
					Total	**25,551**	**100%**

Percentage of Claims that Do/Do Not Require PA for Opioid Dependency Drugs Containing Buprenorphine, July 1, 2018 – March 31, 2019



DHS believes that these data show:

1. Wisconsin Medicaid's PDL is in line with prescribing patterns across the state as 95.34% of prescriptions filled for buprenorphine-containing products are for drugs listed on the PDL.
2. Retaining a PA requirement for non-preferred buprenorphine-containing products does not create an undue barrier to access for Wisconsin Medicaid members since the overwhelming majority of claims are for preferred buprenorphine-containing products, which do not require PA.

Wisconsin Medicaid continues to enforce a diagnosis restriction of opioid dependency on all buprenorphine-containing products since opioid dependency is the only FDA-approved indication for the use of these products. There are no dose limits or duration of treatment constraints on the use of any of these products.

Buprenorphine-Only Products—Used for MAT in Pregnant Women

Buprenorphine-only products are almost exclusively used for MAT in pregnant women, as naloxone is relatively contraindicated during pregnancy, which makes buprenorphine-only products (along with methadone) suitable for expectant mothers.

Wisconsin Medicaid continues to require PA for oral *buprenorphine-only* products. Oral buprenorphine-only products—which lack the abuse deterrent, naloxone—are significantly more prone to misuse. Without naloxone, these products can be manipulated and injected intravenously for euphoria.

PA for the buprenorphine-only products is handled using the specialized transmission approval technology-prior authorization (STAT-PA) automated system. STAT-PA allows providers to request and receive PA electronically so that authorization can be confirmed in a matter of minutes while the member is waiting at the pharmacy. Buprenorphine-only products are authorized when there is an accompanying attestation of current pregnancy and expected delivery date. In the event that the provider has not included details of the pregnancy and delivery date with the prescription, dispensing will not be delayed, as buprenorphine-only products are available through a pharmacist requested "expedited emergency supply" for pregnant women for up to 14 days.

For Medicaid members for whom oral administration of buprenorphine is deemed no longer appropriate or feasible, Wisconsin Medicaid covers buprenorphine-containing products that are provider administered. The buprenorphine implant does not require PA and provides a low, steady dose of the medication for six months. The provider-administered monthly intramuscular injection remains non-preferred due to significantly higher cost but is accessible via PA.

Conclusion

DHS believes the last three quarters of data show that retaining a PA requirement for non-preferred buprenorphine-containing products does not create an undue barrier to access to MAT for Wisconsin Medicaid members. Although PA remains in effect for *non-preferred* buprenorphine-containing products, claims for these drugs represent a small portion of total claims.