Prior Authorization Requirements for Medication Assisted Treatment for Opioid Use Disorder in the Vermont Medicaid Program

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Minimizing Prior Authorization Burden for Providers, Removing Barriers to Medication Assisted Treatment, Reviewing the Data to Assure Timely Access to MAT for Vermont Medicaid Members

Today, we will:

- Discuss the Department of Vermont Health Access' (DVHA's) responsibilities for providing Vermont Medicaid members with the lowest-cost, medically necessary medication for a given disease/condition, as well as the responsibility to Vermont taxpayers to carefully manage Medicaid drug costs;
- Review what the data is telling us about timely access to medication assisted treatment for Vermont Medicaid members; and
- Discuss how the Department of Vermont Health Access (DVHA) has worked collaboratively with providers to minimize prior authorization burden for providers and remove barriers to medication assisted treatment (MAT) of substance use disorders for our members.

State Requirements for Pharmacy Best Practices and Cost Control and Consumer Protection

- The Department of Vermont Health Access (DVHA) utilizes a Preferred Drug list (PDL); this includes medications for Medication Assisted Treatment (MAT) of substance use disorders in accordance with 33 V.S.A. § 1998, Pharmacy Best Practices and Cost Control Program.
  - Allows the use of an evidence-based preferred list of covered prescription drugs.
  - The Drug Utilization Review Board makes recommendations to DVHA based upon evidence-based considerations of clinical efficacy, adverse side effects, safety, appropriate clinical trials and cost-effectiveness.
  - The entire medication assisted treatment class has been reviewed numerous times by the Drug Utilization Review Board, and all prior authorization criteria have been reviewed and approved by the Board.
  - Board is composed of Vermont-based prescribers and pharmacists and currently includes four physicians, and five pharmacists, with an opening for an allied health professional, to ensure broad expertise.
- In addition, DVHA is compliant with 33 V.S.A. § 1999: Consumer protection rules; Prior authorization: this protects consumers and providers from overly burdensome prior authorization requirements and processes.

Legislative Requirement for Annual Report on Prior Authorizations for Medication Assisted Treatment

- Act 43 of 2019, An act relating to limiting prior authorization requirements for medication assisted treatment, was signed by the Governor of Vermont on May 30, 2019. In accordance with Section 4, Prior Authorization for Medication-Assisted Treatment – Medicaid Reports, the Department of Vermont Health Access is required to submit reports on or before February 1st of 2020, 2021, and 2022 regarding Vermont Medicaid's prior authorization processes for medication-assisted treatment.
- The report submitted this year is the third and final report submitted in accordance with the Act.
- Specifically, the Department is required to report on:
  - the medications that required prior authorization;
  - how many prior authorization requests the Department received and of these, how many were approved and denied; and
  - the average and longest lengths of time the Department took to process a prior authorization request.

No Prior Authorization Requirements for . . .

NO prior authorization is required for:

- Methadone used for the treatment of substance use disorder.
- Suboxone Film and buprenorphine/naloxone tabs 24mg or less in the Hubs.
- Suboxone Film and buprenorphine/naloxone tabs 16mg or less in the Spokes. Most patients can be managed at this target dose consistent with current dosing recommendations; nearly 85% of prescriptions are less than 16mg. **(Again, no PA required.)**
- No quantity limits on Suboxone Film 2mg and buprenorphine/naloxone tabs for ease of titration/induction without needing another prior authorization.
- At least one dosage form of every drug marketed for Medication Assisted Treatment is available **without a prior authorization** (methadone, buprenorphine, and naltrexone).
- Narcan (naloxone) Nasal Spray is also available without prior authorization.

Data Tell Us that Vermont Medicaid Members Have Timely Access to Medication Assisted Treatment

- **All prior authorization requests for medication assisted treatment in the Vermont Medicaid program are processed, on average, in 30 minutes.**
- The longest lengths of time for processing prior authorization requests for the buprenorphine therapeutic drug class were 11.95, 8.15, and 6.95 hours.
- All authorizations requests for the year were completed within 24 hours.
- Additionally, there are Emergency 72-hour Overrides available for pharmacies when a prior authorization cannot be obtained in a timely manner.
- Learn more and see the data: https://legislature.vermont.gov/assets/Legislative-Reports/MAT-Prior-Authorization-Report-1-February-2022_DVHA_FINAL.pdf.

Data Tell Us that Vermont Medicaid Members Have Timely Access to Medication Assisted Treatment

Pharmacy Claims and Prior Authorizations 1/1/2021 - 12/31/2021

Therapeutic Drug Class	# Rx Claims Paid	Amount Paid (Gross)	PA Required	Number PAs Approved	Number PAs Denied	PA Approval Percent	PA Denied Percent	Average Determination Time (Hours)	Longest Determination Time (Hours)
BUPRENORPHINE PRODUCTS									
SUBOXONE FILM (BRAND)	106,667	$19,645,250	N*	1,670	53	96.92%	3.08%	0.48	11.95
BUPRENORPHINE HCL/NALOXON SUBL TABLETS	19,441	$616,203	N*	382	9	97.70%	2.30%	0.42	6.95
BUPRENORPHINE HCL SUBL TABLETS(MONO)	8,729	$217,405	Y	603	74	89.07%	10.93%	0.58	8.15
SUBLOCADE SOSY	584	$977,162	Y	254	24	91.37%	8.63%	0.48	2.22
ZUBSOLV SUBL	442	$73,721	Y	62	10	86.11%	13.89%	0.53	4.85
BUPRENORPHINE/NALOXONE FILM**	698	$9,129	Y	13	4	76.47%	23.53%	0.53	2.20
NALTREXONE PRODUCTS									
VIVITROL SUSR	528	$720,535	Y	146	8	94.81%	5.19%	0.50	7.10
NALTREXONE HCL TABS	2,216	$55,011	N	0	0	0.00%	0.00%	0.00	0.00
MISCELLANEOUS PRODUCTS USED FOR ALCOHOL ABSTINENCE									
ACAMPROSATE CALCIUM DR TBEC	581	$52,214	N	0	0	0.00%	0.00%	0.00	0.00
DISULFIRAM TABS	560	$37,758	N	0	0	0.00%	0.00%	0.00	0.00
Total:	140,446	$22,404,386		3,130	182	94.50%	5.50%	0.50	11.95

* PA is only required if the dose is greater than 16mg for "Spokes" or 24mg for "Hubs"

** Medicaid was the secondary payer on all these claims

Why is Buprenorphine Effective in Treating Opioid Use Disorder?

- Partial agonist at opioid receptors.

What does that mean? It means that buprenorphine reduces cravings and withdrawal, and blocks euphoric effects of self-administered illicit opioids through cross tolerance and opioid receptor occupancy.

Is it Safe? Yes, but not for everyone. There is a ceiling effect on opioid activity; therefore, buprenorphine is less likely than methadone or other full agonists to cause respiratory depression.

***** There is a risk of LETHAL overdose with concurrent benzodiazepine, alcohol use or other central nervous system depressants (including dextromethorphan commonly available over-the-counter)*****

What are the Risks Associated with Buprenorphine?

- **Excess doses of Suboxone could be deadly for unintended individuals** and should be considered from a community safety standpoint as well.

- There are multiple studies that highlight the **risk of buprenorphine overdose in children.**

- The ceiling effect seen in adults does not seem to apply to young children **and fatalities can happen.**

<u>One study from the American Academy of Pediatrics found:</u>

"The hospitalization rate for unsupervised ingestion of buprenorphine products was significantly higher than rates for all other commonly implicated medications and 97-fold higher than the rate for oxycodone products (200.1 vs 2.1 hospitalizations per 100 000 unique patients)."

Suboxone Film Dosage Information & Link

Suboxone Film Dosage Information:

- Once daily.
- For patients dependent on short-acting opioid products who are in opioid withdrawal on Day 1, administer up to 8 mg/2 mg Suboxone sublingual film (in divided doses). On Day 2, administer up to 16 mg/4 mg of Suboxone sublingual film as a single dose.
- For patients dependent on methadone or long-acting opioid products, induction onto sublingual buprenorphine monotherapy is recommended on Days 1 and 2 of treatment.
- For maintenance treatment, the target dosage of Suboxone sublingual film is **usually 16 mg/4 mg as a single daily dose**.

Frequently Asked Questions

- **Why can't everyone be managed on 16mg?** For most people, the target dose is 16mg. At 16mg, 97% of receptors are already saturated so there is minimal effect from further increasing the dose. However, dosing may require individualization. This means finding the maintenance dose for the patient that alleviates cravings and withdrawal symptoms without causing sedation. This may require doses up to 24mg, but 16mg is the target for most people.

- **Why are most prior authorizations for buprenorphine dosing over 16mg approved?** If the patient is being treated for a substance use disorder and the prescriber provides documentation of continued cravings, acute withdrawal symptoms and/or relapse, the request for a higher dose is clinically approved.

- **What are reasons for denial of prior authorization?** For the preferred products, most of the prior authorization denials are for coordination of benefits (Vermont Medicaid is not the primary insurance; Vermont Medicaid is required by law to be the payer of last resort) or for dose consolidation.

Prior Authorization Requirements for Medication Assisted Treatment in the Vermont Medicaid Program

- ✓ **The Department of Vermont Health Access requires prior authorizations for its non-preferred products, all of which are clinically reviewed and determined to be equal to or clinically inferior to preferred products and/or more costly for the State of Vermont.***

  Examples: Buprenorphine Mono tablets, Zubsolv®, Sublocade®, and ProBuphine®

  Buprenorphine Formulations:

  - **Oral Formulation**: Buprenorphine "Mono" Formulations, higher street value, higher risk of diversion.
    - No longer recommended for pregnant or breast-feeding mothers.
  - **Injectable:** Sublocade® - a monthly depot injection, 10-15 times the cost of oral formulations.
  - **Implant:** ProBuphine® - 4 surgically inserted rods; 6-month FDA limit.

*Anticipate that removal of prior authorization requirements would have a substantial fiscal impact (see next slide for estimated fiscal impact).

Fiscal Impact of Limiting Prior Authorization Requirements for Medication Assisted Treatment in the Vermont Medicaid Program

The Department's estimated fiscal impact of limiting prior authorizations for medication-assisted treatment in the Vermont Medicaid program consistent with the requirements of H.728 As Recommended by the House Committee on Human Services **is substantial**. The Department of Vermont Health Access anticipates that the provisions within the House Committee on Human Services' committee bill could have an **estimated fiscal impact for the Vermont Medicaid program that ranges from approximately $16.97 million (gross) - $35 million (gross)** based on:

- the loss of supplemental rebates ($4.2 million gross);
- prior authorizations that had previously been denied being newly approved ($688,528 gross); and
- increased utilization of non-preferred medications (for example, the very expensive medication, Sublocade, has minimal rebates; utilization could increase substantially without prior authorization requirements. If the percentage of Medicaid members using that medication increases from 2% to 10% under the policy provision requirements within H.728 As Recommended by the House Committee on Human Services, that alone would result in an estimated fiscal impact of more than $12 million dollars [gross]). However, if the utilization of Sublocade was to increase from 2% to 25%, the estimated fiscal impact for just that change would increase to nearly $30.2 million [gross]).

Drug Spend Data for the Vermont Medicaid Pharmacy Benefit

Buprenorphine products are DVHA's NUMBER ONE for drugs by both Spend and Utilization
*** Includes pharmacy claims only, approximately $1-2 million more in medical claims.**

Therapeutic Class	2020 Gross Paid	2021 Gross Paid	2020 Claim Count	2021 Claim Count	Total Amount Paid Change	Claim Count Change
Opioid Partial Agonists/Substance Abuse Treatments	$19,475,479.14	$21,620,422.66	142,492	139,325	11.0%	-2.2%
Selective Serotonin Reuptake Inhibitors (SSRIS) Antidepressants	$1,285,287.60	$1,383,566.63	82,458	92,375	7.7%	12.0%
Anticonvulsants - Misc.	$4,728,437.50	$4,486,331.96	69,112	74,831	-5.1%	8.3%
Sympathomimetics – Asthma/COPD	$9,988,020.56	$11,264,362.25	64,764	63,960	12.8%	-1.2%
Amphetamines - ADHD	$9,039,029.69	$9,354,230.64	56,147	60,332	3.5%	7.5%
Stimulants – Misc. ADHD	$11,724,319.68	$11,656,455.33	49,755	51,161	-0.6%	2.8%
Proton Pump Inhibitors	$1,319,091.95	$1,349,401.93	33,641	38,431	2.3%	14.2%
Oil Soluble Vitamins[1]	$362,290.52	$399,103.21	34,696	36,986	10.2%	6.6%
Antihistamines – Non-Sedating	$418,004.25	$443,441.75	34,759	36,597	6.1%	5.3%
Opioid Agonists	$1,226,650.79	$1,221,287.81	29,569	31,519	-0.4%	6.6%

Team Care Program – Care Management for Coordinated, High Quality Health Care with Supports

What is the Team Care program?
The Team Care Program is more than a federally-mandated program to prevent misuse, abuse and diversion of medications on the FDA Controlled Substance Schedule, such as opioid pain medications, sedatives, etc.

For Vermont Medicaid members, Team Care Offers Additional Support . . .
Team Care aims to do more than just implement federally mandated restrictions as described above. Vermont's Team Care program is **a care-management initiative** for members who may need additional support to focus their health care services in a way that could be most beneficial to them. The intent of the program is to identify and help to address unmet health care needs, substance use disorder treatment needs, support access to well-coordinated primary and specialty care, and prevent misuse and abuse of regulated medications.

Additionally, for members in recovery from substance use disorder(s), the Team Care Program may be a valuable tool in supporting those members' recovery efforts.

To learn more: https://dvha.vermont.gov/providers/team-care.

Vermont Medicaid Has Removed Barriers to Medication Assisted Treatment Over the Years in Consultation with Providers, Reducing Provider Burden . . .

1) October 2018: The prior authorization requirement for our preferred product (Suboxone® Film) for all providers and for all doses of 16mg and under was removed. This also includes buprenorphine/naloxone tabs.
2) Prior to that, an "auto-PA" was implemented. This process automatically "looks back" through medication and diagnosis history to automatically process a prior authorization. This substantially reduced the number of prior authorizations for medication assisted treatment.
3) Implemented a provider portal through which prior authorizations are "pre-populated" and can be electronically submitted.
4) Launched an e-prescribing solution that displays DVHA's preferred products on the prescriber's electronic medical record and identifies preferred products prior to prescribing.
5) Removed quantity limits on Suboxone Film 2mg and buprenorphine naloxone tabs based on provider feedback, for ease of titration without needing another prior authorization.
6) Days supply allowed increased from 14 days to 30 days.