SmartPA Criteria Proposal

Drug/Drug Class:	Opioid Dependence PDL Edit
First Implementation Date:	April 2, 2015
Proposed Date:	December 17, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: According to the U.S. Department of Health and Human Services (HHS), in 2018, 10.3 million people misused prescription opioids. Of those, 2 million were diagnosed with an Opioid Use Disorder; 47,600 persons died from an opioid overdose. In Missouri in 2017, nearly 2.6 persons died each day from an opioid overdose. Opioid Use Disorder (OUD) is a complex health condition that requires long-term treatment.

Medication Assisted Treatment (MAT) for opioid addiction is effective in facilitating recovery from opioid addiction and has become the standard of care. Use of these pharmacologic agents can help in withdrawal symptoms and reduce cravings of opioids. Buprenorphine, in particular, has a significantly lower risk of respiratory depression unless combined with benzodiazepines. The majority of data suggests that counseling helps to improve treatment outcomes while on buprenorphine/naloxone. Getting affected persons into treatment saves lives and is more likely to lead to full recovery.

MO HealthNet has modified its policies to improve access to Medication-Assisted-Treatment as part of the MO Opioid State Targeted Response (STR) Project.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• **Buprenorphine SL Tabs** • Buprenorphine/Naloxone SL Tabs • Naltrexone Tabs • **Sublocade™** • Suboxone® Film • Vivitrol®	• Bunavail® • Buprenorphine/Naloxone SL Film • **Probuphine®** • Zubsolv®

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Opioid Dependence Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- For Probuphine:
  - Participant aged ≥ 16 years **AND**
  - ~~**Participant claim history in the past 7 days is free of opiates (excluding Medication Assisted Treatment for opioid use disorder) AND**~~
  - Documented diagnosis of opioid use disorder **AND**
  - Participant claim history demonstrates at least 30 days of stable therapy on ≤ 8 mg/day of buprenorphine in the last 90 days **AND**
  - Participant is currently not pregnant **AND**
  - Claim frequency does not exceed 1 claim every 162 days
- For Sublocade:
  - Participant aged ≥ 16 years **AND**
  - ~~**Participant claim history in the past 7 days is free of opiates (excluding Medication Assisted Treatment for opioid use disorder) AND**~~
  - Documented diagnosis of opioid use disorder **AND**
  - Participant claim history demonstrates at least 30 days of stable therapy on buprenorphine in the last 90 days **AND**
  - Claim frequency does not exceed 1 claim every 26 days **AND**
  - Claim frequency for 300mg strength does not exceed 2 claims every 6 months
- For Vivitrol:
  - Participant aged ≥ 16 years **AND**
  - ~~**Participant claim history in the past 7 days is free of opiates (including buprenorphine and methadone) AND**~~
  - Documented diagnosis of alcohol dependence, opioid use disorder or substance use disorder **AND**
  - Participant is currently not pregnant **AND**
  - Claim frequency does not exceed 1 claim every 21 days
- For all other agents not listed above:
  - Participant aged ≥ 16 years **AND**
  - Claim does not exceed max dosing limitations (see Appendix A) **AND**
  - Participant claim history plus incoming claim demonstrates ≤ 24 mg/day of buprenorphine in the past 25 days
- Failure to achieve desired therapeutic outcomes with a trial on **3** preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents **OR**
  - Documented compliance on a current non-preferred therapy regimen (90/120 days)

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

180 days

Appendix A - Opiate Dependence Agents and Dosage Limits

Drug Description	Generic Equivalent	Max Units per Day
BUNAVAIL 2.1-0.3 MG FILM BUCCAL	BUPRENORPHINE HCL/NALOXONE HCL	6
BUNAVAIL 4.2-0.7 MG FILM BUCCAL	BUPRENORPHINE HCL/NALOXONE HCL	3
BUNAVAIL 6.3MG-1MG FILM BUCCAL	BUPRENORPHINE HCL/NALOXONE HCL	2
REVIA 50 MG TABLET	NALTREXONE HCL	1
SUBOXONE 12 MG-3 MG SL FILM	BUPRENORPHINE HCL/NALOXONE HCL	2
SUBOXONE 2 MG-0.5MG SL FILM	BUPRENORPHINE HCL/NALOXONE HCL	12
SUBOXONE 2MG-0.5MG SL TAB	BUPRENORPHINE HCL/NALOXONE HCL	12
SUBOXONE 4MG-1MG SL FILM	BUPRENORPHINE HCL/NALOXONE HCL	6
SUBOXONE 8 MG-2 MG SL FILM	BUPRENORPHINE HCL/NALOXONE HCL	3
SUBOXONE 8MG-2MG SL TAB	BUPRENORPHINE HCL/NALOXONE HCL	3
SUBUTEX 2MG SL TAB	BUPRENORPHINE HCL	12
SUBUTEX 8MG SL TAB	BUPRENORPHINE HCL	3
ZUBSOLV 0.7-0.18 MG SL TAB	BUPRENORPHINE HCL/NALOXONE HCL	24
ZUBSOLV 1.4-0.36MG SL TAB	BUPRENORPHINE HCL/NALOXONE HCL	12
ZUBSOLV 11.4-2.9 MG SL TAB	BUPRENORPHINE HCL/NALOXONE HCL	1
ZUBSOLV 2.9-0.71 MG SL TAB	BUPRENORPHINE HCL/NALOXONE HCL	6
ZUBSOLV 5.7-1.4 MG SL TAB	BUPRENORPHINE HCL/NALOXONE HCL	3
ZUBSOLV 8.6-2.1 MG SL TAB	BUPRENORPHINE HCL/NALOXONE HCL	2

Drug Description	Generic Equivalent	Claim frequency limitation
PROBUPHINE 74.2MG IMPLANT	BUPRENORPHINE HCL	1 EVERY 162 DAYS
SUBLOCADE 100MG/0.5ML SYRINGE	BUPRENORPHINE	1 EVERY 26 DAYS
SUBLOCADE 300MG/1.5ML SYRINGE	BUPRENORPHINE	1 EVERY 26 DAYS
VIVITROL 380MG VIAL	NALTREXONE MICROSPHERES	1 EVERY 21 DAYS

References

1. Missouri Department of Health and Senior Services. Missouri Opioids Information. http://health.mo.gov/data/opioids/ . Website accessed November 2020.
2. National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. American Society of Addiction Medicine (ASAM). Adopted by the ASAM Board of Directors, June 1, 2015.
3. Evidence-Based Medicine Analysis: "Opiate Agonist Dependence", UMKC-DIC; September 2020.
4. Evidence-Based Medicine and Fiscal Analysis: "Opiate Dependence Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; October 2020.
5. Drug Effectiveness Review Project – Briefing Paper: "Opioid Dependency Treatment". Center for Evidence-Based Policy, Oregon Health & Science University; July 2019.
6. Medicaid Evidence-based Decisions Project (MED) Policy Brief - "Buprenorphine for Treatment of Opioid Use Disorder in Primary Care". Center for Evidence-Based Policy, Oregon Health & Science University; August 2014.
7. Medicaid Evidence-based Decisions Project (MED) Report. "Best Practices for State Medication-Assisted Treatment Programs". November 2017" - Center for Evidence-Based Policy, Oregon Health & Science University; November 2017.
8. Missouri Opioid State Target Response (STR) Project. https://missouriopioidstr.org/ Website accessed December 2018.
9. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2019.
10. USPDI, Micromedex; 2020.
11. Drug Facts and Comparisons On-line; 2020.