SmartPA Criteria Proposal

Drug/Drug Class:	Opioids, Long Acting PDL Edit
First Implementation Date:	February 16, 2005
Revised Date:	April 7, 2022
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: Chronic pain, typically defined as pain of at least 6 months in duration, is a common cause of major disability. Opioids are a class of medications that act on common receptors and are natural derivatives of morphine. They are the most potent medications available for treatment of most types of severe pain. Opioids are available in both short- and long-acting preparations and are commonly used for malignant as well as chronic non-malignant pain therapy. Opioid therapy has been endorsed by both national associations and chronic pain specialists as appropriate treatment for refractory chronic non-cancer pain in the general population when used judiciously and according to guidelines similar to those used for cancer patients.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Butrans®	• Belbuca®
• Fentanyl Patch 12, 25, 50, 75, 100 mcg/hr	• Buprenorphine Film/Patch
• Morphine Sulfate ER Tabs (gen MS Contin®)	• Fentanyl Patch 37.5, 62.5, 87.5 mcg/hr
	• Hydrocodone ER
	• Hydromorphone ER
	• Hysingla® ER
	• Kadian®
	• Morphine ER Caps (gen Avinza®)
	• Morphine ER Caps (gen Kadian®)
	• MS Contin®
	• Oxycodone ER Tabs
	• OxyContin®
	• Oxymorphone ER
	• Xtampza® ER

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

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

Setting & Population

- Drug class for review: Opioids, Long Acting
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented diagnosis of cancer in the past 6 months **OR**
- Documented diagnosis of sickle cell disease in the past 6 months **OR**
- Participant currently enrolled in Hospice care or receiving palliative care in the last year **OR**
- Documented compliance to current non-preferred therapy regimen
- Clinical Consultant Review required for participants aged less than 18 years
- ~~**Documented diagnosis of chronic nonmalignant pain (CNMP) in the last 6 months**~~
- **Documented history of > 7 days of opioid therapy in the past 30 days**
- Failure to achieve desired therapeutic outcomes with a trial on 3 or more preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents
- ~~**For fentanyl patch doses ≥ 50 mcg/hr and oxycodone ER 80 mg: inferred diagnosis of opioid tolerance (> 7 day supply in the last 30 days)**~~
- Participant must also meet all approval criteria contained within the Morphine Milligram Equivalent Accumulation Clinical Edit

Denial Criteria

- Lack of adequate trial on required preferred agents
- Documented opioid dependence therapy in the last 45 days
- **Documented Lybalvi therapy in the past 45 days**
- Denial criteria contained within the High Risk Therapies Clinical Edit: Claim is for an opioid (excluding buprenorphine tablets and buprenorphine/naloxone combinations) and:
  - Participant has history of > 3 days of **oral benzodiazepine therapy** in the past 60 days **OR**
  - **Participant has history of > 3 days of select sedative hypnotic therapy (eszopiclone, zaleplon, or zolpidem) in the past 60 days OR**
  - **Participant has history of > 3 days of gabapentinoid therapy (gabapentin or pregabalin) in the past 60 days AND**
  - Participant lacks history of at least 1 claim for an opioid emergency reversal agent in the past 2 years
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitations for the following:

Drug Description	Generic Equivalent	Max Units Per Day
FENTANYL 12 MCG/HR PATCH	FENTANYL TRANSDERMAL	1 patch
FENTANYL 25 MCG/HR PATCH	FENTANYL TRANSDERMAL	1 patch
FENTANYL 37.5 MCG/HR PATCH	FENTANYL TRANSDERMAL	1 patch
FENTANYL 50 MCG/HR PATCH	FENTANYL TRANSDERMAL	1 patch
FENTANYL 62.5 MCG/HR PATCH	FENTANYL TRANSDERMAL	1 patch
FENTANYL 75 MCG/HR PATCH	FENTANYL TRANSDERMAL	1 patch
FENTANYL 87.5 MCG/HR PATCH	FENTANYL TRANSDERMAL	1 patch
FENTANYL 100 MCG/HR PATCH	FENTANYL TRANSDERMAL	1 patch
OXYCONTIN 10 MG TABLETS	**OXYCODONE HYDROCHLORIDE**	**3 tablets**
OXYCONTIN 15 MG TABLETS	**OXYCODONE HYDROCHLORIDE**	**3 tablets**
OXYCONTIN 20 MG TABLETS	**OXYCODONE HYDROCHLORIDE**	**3 tablets**
OXYCONTIN 30 MG TABLETS	**OXYCODONE HYDROCHLORIDE**	**3 tablets**

OXYCONTIN 40 MG TABLETS	OXYCODONE HYDROCHLORIDE	3 tablets
OXYCONTIN 60 MG TABLETS	OXYCODONE HYDROCHLORIDE	3 tablets
OXYCONTIN 80 MG TABLETS	OXYCODONE HYDROCHLORIDE	3 tablets

Required Documentation

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

Disposition of Edit

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

Default Approval Period

6 months

References

- Evidence-Based Medicine and Fiscal Analysis: “Opioids, Long-Acting Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: “Long-Acting Opioids”, UMKC-DIC; August 2021.
- Medicaid Evidence-Based Decisions Project – Tapering or Discontinuing Opioid Use among Patients with Chronic Noncancer Pain (Rapid Review). Center for Evidence-Based Policy, Oregon Health & Science University; October 2017.
- USPDI, Micromedex; 2021.
- Drug Facts and Comparisons On-line; 2021.