SmartPA Criteria Proposal

Drug/Drug Class:	High Risk Therapies Clinical Edit
First Implementation Date:	April 15, 2021
Revised Date:	N/A
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure the presence of opioid emergency reversal agents in high risk medication therapies

Why Issue Selected: With the implementation of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, state Medicaid programs have new requirements regarding prescription drug utilization reviews. MO HealthNet is introducing new processes to monitor concurrent prescribing of opioids, benzodiazepines and antipsychotics to meet the above requirements.

The combination of opioids and benzodiazepines is considered a high risk therapy as both drugs cause sedation, impaired cognitive function, and respiratory depression potentially leading to an overdose fatality. Unfortunately, many patients are still prescribed this high risk therapy combination. In 2015, 23% of opioid overdose fatalities also tested positive for benzodiazepines. Also, the number of patients prescribed both an opioid and a benzodiazepine increased by 41% between 2002 and 2014. In March 2016, the CDC released their Guideline for Prescribing Opioids for Chronic Pain; further clarification of these guidelines was published in April 2019. These guidelines recommend avoiding the prescribing of benzodiazepines concurrently with opioids whenever possible. Also, both opioids and benzodiazepine prescription products now carry a boxed warning from the FDA highlighting the danger of using these agents together.

Naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Pharmacists in Missouri are able to dispense naloxone according to protocol upon request or upon presentation of a valid prescription. As part of the efforts to protect participants from the possible adverse effects of combining opioid and benzodiazepine medications, MO HealthNet will impose clinical criteria to require the presence of an opioid emergency reversal agent, such as naloxone, when these agents are used concomitantly.

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: High risk medication therapies
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Participant has documented history of at least 1 claim for an opioid emergency reversal agent in the past 2 years

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim is for an opioid (excluding buprenorphine tablets and buprenorphine/naloxone combinations) and:
  - Participant has history of > 3 days of select oral benzodiazepine therapy (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, lorazepam, and oxazepam) 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
- Claim is for a select oral benzodiazepine (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, lorazepam, and oxazepam) and:
  - Participant has history of > 7 days of opioid therapy (excluding buprenorphine tablets and buprenorphine/naloxone combinations) 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

Required Documentation

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

Disposition of Edit

Denial: Exception code “0234” (Dose Optimization)
Rule Type: PD

Default Approval Period

7 days

References

- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act 2018. Available at: https://www.congress.gov/bill/115th-congress/house-bill/6
- FDA News Release. FDA requires strong warnings for opioid analgesics, prescription opioid cough products, and benzodiazepine labeling related to serious risks and death from combined use. https://www.fda.gov/news-events/press-announcements/fda-requires-strong-warnings-opioid-analgesics-prescription-opioid-cough-products-and-benzodiazepine. August 31, 2016.

- NIH: National Institute on Drug Abuse. Benzodiazepines and Opioids. https://www.drugabuse.gov/drug-topics/opioids/benzodiazepines-opioids. March 15, 2018.
- Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1