SmartPA Criteria Proposal

Drug/Drug Class:	High Risk Therapies Clinical Edit
First Implementation Date:	April 15, 2021
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: 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 CNS depressants (i.e., benzodiazepines, sedative hypnotics, and gabapentinoids) is considered a high risk therapy as both may cause sedation, impaired cognitive function, and respiratory depression potentially leading to an overdose fatality. Unfortunately, many patients are still prescribed these high risk therapy combinations. In 2016, the CDC released their Guideline for Prescribing Opioids for Chronic Pain; further clarification of these guidelines was published in 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. In 2019, the FDA also added a boxed warning to gabapentinoid agents on the risk of respiratory depression when used alone or with opioids. Recently, several studies have pointed to an increased risk of overdose when combining non-benzodiazepine sedative hypnotics with opioid therapy, especially the “z-drugs” zolpidem, zaleplon, and eszopiclone.

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. A statewide Standing Order issued by the Missouri Department of Health and Senior Services is available at https://pr.mo.gov/boards/pharmacy/NaloxoneStandingOrder.pdf. As part of the efforts to protect participants from the possible adverse effects of combining opioid and CNS depressant 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 **OR**
- **Claim is for a 1 day supply**

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 **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
- Claim is for **an oral benzodiazepine**, **a select sedative hypnotic (eszopiclone, zaleplon, or zolpidem), or a gabapentinoid (gabapentin or pregabalin)** 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 “1014” (High Risk Combination Edit)
Rule Type: PD

Default Approval Period

7 days

References

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- 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.
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- Department of Health & Human Services. Centers for Medicare & Medicaid Services. Investigations and Audits Group. Opioid Potentiators. March 16, 2018. CMS letter about opioid Potentiators.pdf (cmda.us)
- Ray WA, Chung CP, Murray KT, Malow BA, Daugherty JR, et al. (2021) Mortality and concurrent use of opioids and hypnotics in older patients: A retrospective cohort study. PLOS Medicine 18(7): e1003709. https://doi.org/10.1371/journal.pmed.1003709
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- FDA News Release. FDA In Brief: FDA requires new warnings for gabapentinoids about risk of respiratory depression. December 19, 2019. FDA In Brief: FDA requires new warnings for gabapentinoids about risk of respiratory depression | FDA