SmartPA Criteria Proposal

Drug/Drug Class:	Sedative Hypnotics PDL Edit
First Implementation Date:	November 9, 2005
Proposed Date:	December 15, 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: Insomnia often presents with one or more of the following symptoms: difficulty falling asleep, waking up often during the night and having trouble going back to sleep, waking up too early in the morning, or unrefreshing sleep. These symptoms can cause problems during the day, such as sleepiness, fatigue, difficulty concentrating, and irritability. Patients with insomnia may also have another sleep disorder such as sleep apnea, narcolepsy, or restless legs syndrome. About 60 million Americans suffer from insomnia each year, affecting 40% of women and 30% of men, with incidence tending to increase with age.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Doxepin 10, 25, 50, 75, 100, 150 mg Caps • Eszopiclone • Temazepam 15, 30 mg • Zaleplon • Zolpidem Tabs	• Ambien® • Ambien CR® • Belsomra® • Dayvigo® • Doxepin 3, 6 mg Tabs • Edluar® • Estazolam • Flurazepam • Halcion® • Hetlioz® • Lunesta® • Midazolam Syrup • **Quviviq™** • Ramelteon • Restoril™ • Rozerem® • Silenor® • Temazepam 7.5, 22.5 mg • Triazolam • Zolpidem ER • Zolpidem SL

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: Sedative Hypnotics
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Claim is for doxepin capsules **OR**
- Documented compliance on current therapy regimen (90/180 days) for participants on only 1 sedative hypnotic (must also be a preferred agent) dosed at no more than 1 unit per day **OR**
- Participants aged 18 years or older **AND**
- Participants with no history of sedative hypnotic therapy within the past 90 days limited to 15-day supply with first and second fills **OR**
- Participants with history of sedative hypnotic therapy (defined as ≥ 30 days of therapy within the last 90 days) require documented diagnosis of insomnia or chronic insomnia within the last 2 years **AND**
- For non-preferred agents: Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents **AND**
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents
- For midazolam syrup: Clinical Consultant Review required for claims > 1 day supply
- For Dayvigo: documented therapeutic trial of Belsomra (trial defined as 30 days)
- **For Quviviq: documented therapeutic trial of both Belsomra and Dayvigo (trial defined as 30 days)**

Denial Criteria

- History of substance misuse in the last 2 years
  - **Participants with a history of substance misuse may access doxepin capsules, melatonin, or Rozerem.**
  - **Belsomra is available to participants with a history of substance misuse after:**
    - **Documentation of therapeutic trial of doxepin capsules AND**
    - **Documentation of therapeutic trial of either melatonin or Rozerem AND**
    - **Subject to Clinical Consultant Review**
- Participants receiving > 1 concurrent sedative hypnotic in the last 3 months
- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Denial criteria contained within the High Risk Therapies Clinical Edit: Claim is for an oral benzodiazepine or select sedative hypnotic (eszopiclone, zaleplon, or zolpidem) 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
- Claim exceeds maximum dosing limitations for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
AMBIEN 10 MG TABLET	ZOLPIDEM TARTRATE	1 tablet per day
AMBIEN 5 MG TABLET	ZOLPIDEM TARTRATE	1 tablet per day
AMBIEN CR 12.5 MG TABLET	ZOLPIDEM TARTRATE	1 tablet per day

AMBIEN CR 6.25 MG TABLET	ZOLPIDEM TARTRATE	1 tablet per day
BELSOMRA 10 MG TABLET	SUVOREXANT	1 tablet per day
BELSOMRA 15 MG TABLET	SUVOREXANT	1 tablet per day
BELSOMRA 20 MG TABLET	SUVOREXANT	1 tablet per day
BELSOMRA 5 MG TABLET	SUVOREXANT	1 tablet per day
DAYVIGO 10 MG TABLET	LEMBOREXANT	1 tablet per day
DAYVIGO 5 MG TABLET	LEMBOREXANT	1 tablet per day
EDLUAR 10 MG SL TABLET	ZOLPIDEM TARTRATE	1 tablet per day
EDLUAR 5 MG SL TABLET	ZOLPIDEM TARTRATE	1 tablet per day
ESTAZOLAM 1 MG TABLET	ESTAZOLAM	1 tablet per day
ESTAZOLAM 2 MG TABLET	ESTAZOLAM	1 tablet per day
FLURAZEPAM 15 MG CAPSULE	FLURAZEPAM	1 capsule per day
FLURAZEPAM 30 MG CAPSULE	FLURAZEPAM	1 capsule per day
HALCION 0.25 MG TABLET	TRIAZOLAM	1 tablet per day
HETLIOZ 20 MG CAPSULE	TASIMELTEON	1 capsule per day
INTERMEZZO 1.75 MG TAB SUBLING	ZOLPIDEM TARTRATE	1 tablet per day
INTERMEZZO 3.5 MG TAB SUBLING	ZOLPIDEM TARTRATE	1 tablet per day
LUNESTA 1 MG TABLET	ESZOPICLONE	1 tablet per day
LUNESTA 2 MG TABLET	ESZOPICLONE	1 tablet per day
LUNESTA 3 MG TABLET	ESZOPICLONE	1 tablet per day
QUVIVIQ 25 MG TABLET	**DARIDOREXANT HCL**	**1 tablet per day**
QUVIVIQ 50 MG TABLET	**DARIDOREXANT HCL**	**1 tablet per day**
RESTORIL 15 MG CAPSULE	TEMAZEPAM	1 capsule per day
RESTORIL 22.5 MG CAPSULE	TEMAZEPAM	1 capsule per day
RESTORIL 30 MG CAPSULE	TEMAZEPAM	1 capsule per day
RESTORIL 7.5 MG CAPSULE	TEMAZEPAM	1 capsule per day
ROZEREM 8 MG TABLET	RAMELTEON	1 tablet per day
SILENOR 3 MG TABLET	DOXEPIN	1 tablet per day
SILENOR 6 MG TABLET	DOXEPIN	1 tablet per day
SONATA 10 MG CAPSULE	ZALEPLON	1 capsule per day
SONATA 5 MG CAPSULE	ZALEPLON	1 capsule per day
TRIAZOLAM 0.125 MG TABLET	TRIAZOLAM	1 tablet per day
ZOLPIMIST 5 MG ORAL SPRAY	ZOLPIDEM TARTRATE	1 spray pump per day

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

6 months

References

- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: CENTRAL NERVOUS SYSTEM: Sedative Hypnotics, Non-Benzodiazepines”, Gainwell Technologies; Last updated October 26, 2022.

- Evidence-Based Medicine and Fiscal Analysis: “Sedative Hypnotics – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: “Sedatives and Hypnotics”, UMKC-DIC; August 2022.
- USPDI, Micromedex; 2022.
- Drug Facts and Comparisons On-Line: 2022.