SmartPA Criteria Proposal

Drug/Drug Class:	Sedative Hypnotics PDL Edit
First Implementation Date:	November 9, 2005
Revised Date:	April 1, 2021
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. While insomnia is not defined by the number of hours a person sleeps every night, most people need between 7 and 8 hours of sleep total per night. About 60 million Americans suffer 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, 150mg Caps** • Eszopiclone • Temazepam 15, 30mg • Zaleplon • Zolpidem Tabs	• Ambien® • Ambien CR® • Belsomra® • **Dayvigo™** • **Doxepin 3, 6mg Tabs** • Edluar® • Estazolam • Flurazepam • Halcion® • Hetlioz® • Intermezzo® • Lunesta® • Midazolam Syrup • Ramelteon • Restoril™ • Rozerem® • Silenor® • Temazepam 7.5, 22.5mg • Triazolam • Zolpidem ER • Zolpidem SL

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: 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**
- 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: participant has a documented therapeutic trial of Belsomra (trial defined as 30 days)**
- Approval of prior authorization is 6 months

Denial Criteria

- History of substance misuse in the last 2 years
- 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
- Claim exceed 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
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

1. Drug Effectiveness Review Project – Drug Class Review on “Insomnia Drugs, Newer”. Center for Evidence-Based Policy, Oregon Health & Science University; October 2009; Evidence Scan, February 2017.
2. Evidence-Based Medicine and Fiscal Analysis: “Sedative Hypnotics – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2020.
3. Evidence-Based Medicine Analysis: “Sedatives and Hypnotics: Treatment for Insomnia”, UMKC-DIC; August 2020.
4. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2019.
5. USPDI, Micromedex; 2020.
6. Drug Facts and Comparisons On-Line: 2020.