Utah Department of Health & Human Services

Pharmacy & Therapeutics Committee

Meeting Minutes

Thursday, September 15, 2022
7:00 a.m. to 8:45 a.m.
Google Meet

Committee Members Present:

Cole Sloan, PharmD
Bryan Larson, PharmD
Christopher Valentine, MD
Clayton Grace, RPh
Clinton Sheffield, MD
McKay Robinson, PharmD
Susan Siegfreid, MD
Michelle Hofmann, MD

Dept. of Health/Div. of Health Care Financing Staff Present:

Lisa Angelos, Pharmacy Director
Jim Stamos, OHPA Director
Joe Busby, RPh, MBA
Luis Moreno, PharmD
Ngan Huynh, PharmD
Misha Goodell, CPhT
Spencer Miller, CPhT

University of Utah Drug Regimen Review Center Staff Presenter:

Monet Luloh, PharmD

Other Individuals Present:

Amy Hale
Charlie Lovan, AbbVie
Fran Reis
Lisa Pulver
Samantha Eshelman, SelectHealth
Valerie Gonzales, UofU

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Meeting conducted by: Committee Chair

1. **Welcome & Housekeeping:** Welcome: Bryan Larson announced a Quorum. Cole Sloan opened the meeting.

2. **Review and Approval of May Minutes:** Bryan Larson made a motion to approve the minutes from May. Cole Sloan seconded the motion. All in favor, motion passed.

3. **Housekeeping**: Introduction of Lisa Angelos as Utah Medicaid Pharmacy Director. McKay Robinson nominated Cole Sloan as P&T Chair. Bryan Larson seconded the motion. All in favor, motion passed.

4. **Drug Utilization Review (DUR) Board update:** The DUR board met in June to discuss Treatment for Insomnia in Pediatric Patients, including consideration of coverage of melatonin. The DUR board met in August to discuss CDC Clinical Practice Guideline for Prescribing Opioids. The DUR board met in September to discuss Mounjaro.

5. **Sedative Hypnotics (Non-benzodiazepines, non-barbiturates):** Presented by Monet Luloh, PharmD from the University of Utah.
    a. According to the International Classification of Sleep Disorders, Third Edition (ICSD-3), insomnia is defined as trouble initiating or maintaining sleep that results in symptoms while awake and occurs despite a suitable sleep environment and adequate opportunity to sleep. Insomnia may occur independently, or comorbidly with other conditions (e.g., sleep apnea, anxiety, depression, chronic pain). N24SWD occurs when an individual is unable to maintain entrainment between their endogenous circadian clock and the 24-hour environment, often due to the inability to perceive light, a key entrainment cue. SMS is a rare, genetic neurodevelopmental disorder that often results.
    b. Two new orexin receptor antagonists (ORAs) have been approved by the US Food and Drug Administration (FDA): daridorexant (Quviviq) and Lemborexant (Dayvigo) since the last P&T report.

c. All of the nBH agents indicated for insomnia are approved for sleep onset insomnia, except Doxepin. The ORAs, controlled-release zolpidem, doxepin, and eszopiclone are approved for sleep maintenance insomnia. A sublingual formulation of zolpidem, Intermezzo, is uniquely indicated for trouble falling back asleep after awakening in the middle of the night. Tasimelteon, oral capsule (Hetlioz), is the only FDA-approved agent for the treatment of N24SWD in adults. It is also approved for the treatment of sleep disturbances in SMS for patients 16 years of age and older, and as an oral suspension (Hetlioz LQ) for children ages 3 to 15 years.

d. Label warnings and precautions for the z-drugs, doxepin, ramelteon, and ORAs include the following:
    1. Recommendation to re-evaluate for potential comorbid conditions if insomnia fails to remit after 7-10 days on pharmacotherapy.
    2. Recommendation to evaluate for worsening depression or suicidal ideation.
    3. Elevated risk of next-day impairment, especially when used in combination with CNS depressants (e.g., opioids, alcohol, benzodiazepines).
    4. Elevated risk of complex sleep behaviors (e.g., sleep-driving, sleep walking).

e. Regarding the Utah Medicaid PDL, the P&T Committee may consider the following recommendations:
    1. Reaffirmation of our previous 2019 P&T board recommendation to have at least 1 hypnotic preferred for sleep onset insomnia and at least 1 agent preferred for sleep maintenance insomnia
    2. Consider including at least 1 non-controlled hypnotic as preferred for sleep onset or sleep maintenance insomnia:
        1. The z-drugs and ORAs are classified as Schedule IV controlled substances due to the potential increased risk of abuse.
        2. Ramelteon and doxepin are both non-controlled substances; however, ramelteon is approved only

for sleep onset insomnia in adults, whereas low-dose doxepin formulations (6 mg or less; brand Silenor) are approved for sleep maintenance insomnia in adults.

3. Higher strength formulations of doxepin (e.g., 10 mg) - are not approved for insomnia.

6. **Public Comment:** No public comment.

7. **Committee Discussion:** Cole Sloan made a motion to have at least one noncontrolled hypnotic as preferred for sleep onset or sleep maintenance insomnia. Susan Siegfreid seconded. All in favor, motion passed.

8. **Public Meeting Adjourned**: Bryan Larson motioned to close the meeting. Clayton Grace seconded the motion. All approved, motion passed.

9. **Google Meeting Chat Log**:

   Cole Sloan7:01 AM: will hop off and try again

   Joe Busby (DHHS)7:04 AM: For our non-committee member guests: please enter your affiliation information here in the chat or via e-mail to medicaidpharmacy@utah.gov

   Samantha Eshelman7:04 AM: SelectHealth

10. **Next meeting is scheduled for** November 17, 2022**. Topic:** TBD

Audio recording of all P&T meetings are available online at: https://medicaid.utah.gov/pharmacy/pt-committee?p=Committee%20Meeting%20Audio%20Recordings