Utah Department of Health & Human Services

# Drug Utilization Review Board

Meeting Minutes

**Thursday, May 12, 2022**
**7:15 a.m. to 8:30 a.m.**
**Google Meet**

**Board Members Present:**

Eric Cannon, PharmD, FAMCP, Board Chair
Jennifer Brinton, MD
Judith Turner, DVM, PharmD
Katherine Smith, PharmD
Kyle Kitchen, PharmD
Michelle Hofmann, MD
Neal Catalano, PharmD
Sharon Weinstein, MD
Susan Siegfreid, MD

**Board Members Excused:**

Elizabeth Gargaro, MD
Kumar Shah, MSc, PEng

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

Jennifer Strohecker, PharmD, Medicaid Director
Bryan Larson, PharmD
James Stamos, Office Director
Joe Busby, RPh, MBA
Julie Armstrong, CPhT
Katie Gilliland, CPhT
Luis Moreno, PharmD
Ngan Huynh, PharmD
Stephanie Byrne, PharmD

**University of Utah Drug Regimen Review Center Staff Presenter:**

Monet Luloh, PharmD U of U DRRC

**Other Individuals Present:**

Beth W.
Carrie Johnson, PharmD Amgen
Chris Heath, Medtronic
Heidi Goodrich, Molina Healthcare
Jason Smith, Gilead Sciences
Joanne Lafleur, PharmD U of U DRRC
Kelvin Yamashita, Sanofi Genzyme
Kendrick LaFleur, Odyssey House
Lindsey Walter, Novartis
Lisa Angelos, Change Healthcare
Madeline Shurtleff, Otsuka
Michael Zarob, Merck
Valerie Gonzales, PharmD U of U DRRC
Veena Nowakowski, Genetech

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**Meeting conducted by:** Eric Cannon

1. **Welcome:** Ngan Huynh opened the meeting and reminded everyone who attended the meeting to identify themselves via meeting chat or by sending an email to medicaidpharmacy@utah.gov. Ngan Huynh announced a quorum.

2. **Review and Approval of April Minutes:** Neal Catalano motioned to approve the minutes from April as drafted. Sharon Weinstein seconded the motion. Unanimous approval. Judith Turner was not present for vote.

3. **Housekeeping:** Jennifer Strohecker stated legislation approved funding for two pharmacy related services.
    I. Reimbursements will be paid for medication therapy management (MTM) consult and related services provided by pharmacists. Services will be focused on chronic conditions. The policy is being prepared for external stakeholder input and review by the Drug Utilization Review Board. Utah Medicaid will work collectively with the Accountable Care Organizations to refine the policy prior to board review and July 1, 2022, go live. Sharon Weinstein inquired if chronic pain would qualify under chronic conditions. Jennifer Strohecker stated chronic pain could be included.

    II. Funding has been approved for all prediabetic Medicaid members to be enrolled in a national diabetes prevention program that is certified and recognized by the Centers for Disease Control (CDC) that will allow them to receive counceling, coaching and educational services in group settings (in person and virtual).

    The Pharmacy Director position will be posted in the next couple of weeks to replace Jennifer Strohecker for interested individuals to apply.

4. **Tezspire (tezepelumab):**
    a. **Information:** Monet Luloh, PharmD from the University of Utah DRRC presented peer-reviewed research regarding indications for

use, safety and efficacy, treatment guidelines, and considerations for prior authorization criteria for the newly approved monoclonal antibody Tezspire (tezepelumab) for the treatment of severe asthma (non-type II phenotype). Asthma is a complex, heterogeneous respiratory disease characterized by chronic inflammation leading to narrowing of the airways. Severity depends on frequency of symptoms and exacerbations. Severe asthma is known to reduce patient quality of life, and although it only accounts for five to ten percent of all asthma diagnoses, it accounts for greater than sixty percent of total asthma expenditures. Biologics are typically reserved for difficult to treat or severe asthma. Clinical trials showed a decreased rate of exacerbations regardless of baseline eosinophil concentration or allergic status. Tezspire (tezepelumab) was well tolerated compared to placebo in clinical trials. The most common adverse effects included pharyngitis, arthralgia, back pain, and injection site reactions. Clinical trials did not require patients to meet certain biological marker thresholds for enrollment. Considerations for prior authorization criteria include use in patients twelve years of age or older, a diagnosis of severe asthma, add-on maintenance treatment, consultation with a provider specialized in treating severe asthma, administration by a provider in a healthcare setting, and inadequate response to a preferred first line therapy.

b. **Public Comment:** Carrie Johnson, Pharm D from Amgen provided testimony on the clinical information for Tezspire (tezepelumab).
c. **Board Discussion:** Ngan Huynh presented the proposed prior authorization criteria for Anti-asthmatic Monoclonal Antibodies and utilization data. Utah Medicaid does not have any current patients on Tezspire (tezepelumab) or Nucala. Less than five patients are on Xolair and Fasenra. The majority of patients are currently established on Dupixent. Neal Catalano inquired if the Anti-asthmatic Monoclonal Antibodies form has been meeting the needs for Utah Medicaid patients. Ngan Huynh stated the form has been revised as new monoclonal antibodies become available. The previous table was removed so each product can follow the package insert. Ngan Huynh stated the form is currently meeting Utah Medicaid's needs.

**Criteria for Approval (all criteria must be met and documented in submitted chart notes):**

- ❑ Medication is prescribed by or in consultation with a physician who specializes in the disease treatment.
- ❑ Documentation of FDA approved diagnosis: _____ Chart Note Page #: _____
  - Allergen testing, if applicable. Chart Note Page #: _____
  - Other confirmation testing, if applicable. Chart Note Page #: _____
- ❑ Use must follow FDA-approved labeling *(including monitoring for boxed warnings and contraindications).*
  - Applicable monitoring for boxed warnings. Chart Note Page #: _____
- ❑ Documentation of appropriate first line treatments or interventions, if current treatment standards recommend other treatment modalities or interventions prior to use of the requested drug. Chart Note Page #: _____

**Non-Preferred Product:** *(Criteria above must also be met)*

- ❑ Minimum 3-month trial and failure of at least one preferred product in this therapeutic class, or prescriber must demonstrate medical necessity for non-preferred product.
  Medication(s): _____ Chart Note Page #: _____
  Dates of therapy: _____ Details of Failure: _____

**Off Label or Compendia Use of FDA-Approved Drugs Additional Criterion:**
Requests for any off-label indications must be supported by at least one (1) major multi-site study or three (3) smaller studies published in JAMA, NEJM, Lancet or other peer review specialty medical journals within the most recent five (5) years. Supporting documentation must be included. Compendia use must be recommended by generally-accepted compendia such as American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (USP-DI), and the DRUGDEX Information System.
Diagnosis: _____ Duration of treatment: _____

**Re-authorization Criteria:** *Please submit pre-treatment and current information*
Updated letter with medical justification or updated chart notes demonstrating positive clinical response.

**Initial Authorization:** Up to six (6) months
**Re-authorization:** Up to one (1) year

**Notes:**

- ❖ Use appropriate HCPCS code for billing
  Coverage and Reimbursement code look up: https://health.utah.gov/stplan/lookup/CoverageLookup.php
  HCPCS NDC Crosswalk: https://health.utah.gov/stplan/lookup/FeeScheduleDownload.php
- ❖ Patient must have regular appointments to receive or follow up on the medication in the prescriber's office. The patient must remain in the office for an adequate amount of time to allow for observation and treatment of anaphylaxis, if necessary. If/when any change of dose is requested, the prescriber must indicate, in writing, the reasoning for the dose increase.

d. **Board Action:** Sharon Weinstein motioned to approve the prior authorization criteria. Katherine Smith seconded the motion. Unanimous approval. Eric Cannon recommended reviewing criteria and utilization data in a year as the category grows and expense to the state increases.

5. **Hetlioz (tasimelteon):**
   a. **Information:** Luis Moreno presented peer-reviewed research regarding background on normal circadian rhythm, mechanism of action and formulations, non-twenty-four-hour sleep-wake disorder, nighttime sleep disturbances in Smith-Magenis Syndrome (SMS), place in therapy, claims and prior authorization history, and recommendations for Hetlioz (tasimelteon). Endogenous circadian rhythms are regulated by the suprachiasmatic nucleus (SCN) in the brain. Circadian rhythms are usually longer than twenty-four hours and require daily synchronization. The primary means to keep the suprachiasmatic nucleus (SCN) aligned is via light-dark exposure through specialized cells in the retina called retinal ganglion cells.

Hetlioz (tasimelteon) is a melatonin receptor agonist. According to the package insert the drug effect may not occur for weeks or months. Non-twenty-four-hour sleep-wake disorder is a rare circadian rhythm disorder in which the patient experiences constant shifts and/or delays in the sleep-wake cycle. The rare condition primarily affects blind individuals lacking light perception or sighted individuals with impairment in the circadian response to light. Clinical trials showed decreased daytime sleep duration by one hour per day and increased night-time sleep by one hour per day. The most common adverse effects included headache, increased liver enzymes (ALT levels), nightmares, urinary tract infections, and upper respiratory tract infections. Hetlioz (tasimelteon) can interact with CYP1A2 inhibitors, CYP3A4 inducers, beta-adrenergic receptor antagonists, and benzodiazepine and non-benzodiazepine hypnotics. Smith-Magenis Syndrome (SMS) is a developmental disorder caused by a deletion in chromosome 17p11.2 or mutations in the retinoic acid-induced 1 (RAI1) gene. Smith-Magenis Syndrome (SMS) sleep disturbances are due to an inverted circadian rhythm where melatonin rises during the day and falls during the night. Hetlioz (tasimelteon) significantly improved the overall total nighttime sleep duration. Melatonin is recommended as a first line therapy. Hetlioz (tasimelteon) is an option for non-twenty-four-hour blind adults who do not respond to melatonin. Utah Medicaid does not have any current patients on Hetlioz (tasimelteon). Six prior authorization requests have been received and denied for missing required documentation from healthcare provider. Katherine Smith inquired how many people dropped out of the clinical trials due to side effects or adverse effects. Luis Moreno stated there ten individuals that dropped out of the clinical trials, none were due to side effects or adverse effects. Eric Cannon stated the first trial was only studied in blind individuals. The clinical trials did not require individuals to have a trial of melatonin. Susan Siegfreid stated urinary melatonin metabolite was measured which is not something clinicians do on a regular basis.

b. **Board Discussion:** Luis Moreno presented the proposed prior

authorization criteria for Hetlioz (tasimelteon).

**Criteria for Approval:** *(all of the following criteria must be met)*

- ❑ Prescribed by, or in consultation with a physician board certified with The American Board of Sleep Medicine.
- ❑ Diagnosis of "non-24-hour sleep-wake rhythm disorder" with total blindness and complete absence of light perception **OR** nighttime sleep disturbances in Smith-Magenis Syndrome in patients 3 years of age or older. Chart Note Page #: _____
- ❑ Symptoms cannot be better explained by another current sleep, medical, neurologic, mental, substance use disorder, or medication use. Please describe process used to rule out each potential confounding factor. Chart Note Page #: _____
- ❑ Documentation that behavioral modifications (e.g. regular sleep schedule) have been implemented. Chart Note Page #: _____
- ❑ Failure of at least a 3-month trial of USP-verified melatonin OR intolerance to melatonin. Chart Note Page #: _____

**Additional Criteria for Non-24-Hour Sleep-Wake Rhythm Disorder:**

- ❑ History of insomnia and/or excessive daytime sleepiness, that alternates with time periods of being asymptomatic, as the individual rotates between alignment and misalignment with the environmental light-dark schedule. Chart Note Page #: _____
- ❑ Symptoms documented as being present for at least three months. Chart Note Page #: _____
- ❑ Daily sleep logs and actigraphy for at least 14 days demonstrating a gradual daily drift (typically later) in rest-activity patterns. Chart Note Page #: _____

**Additional Criteria for Nighttime Sleep Disturbances in Smith-Magenis Syndrome**:

- ❑ Documentation of genetic testing (deletion 17p11.2 OR *RAI*1 gene mutation). Chart Note Page #: _____
- ❑ History of sleep disturbances. Chart Note Page #: _____

**Re-authorization Criteria:**

- ❖ Updated letter of medical necessity or updated chart notes demonstrating positive clinical response.
- ❖ Provider attests to reviewing Hetlioz adherence goals with the patient at each visit.

**Authorization:** Up to three (3) months
**Re-authorization:** Up to one (1) year

Note:

- ❖ Concomitant use of Hetlioz with the following agents may put the patient at risk of side effects from Hetlioz or a subtherapeutic effect: melatonin or other non-benzodiazepine hypnotics, benzodiazepines, strong CYP1A2 inhibitors (e.g., fluvoxamine), or strong CYP3A4 inducers (e.g., rifampin)

Eric Cannon inquired if requiring a one-month trial of melatonin is long enough. Eric Cannon recommended requiring a three-month trial consistent with package labeling. Susan Siegfreid agreed requiring a three-month trial is more appropriate. Valerie Gonzales inquired if melatonin is covered under the Utah Medicaid pharmacy benefit. Bryan Larson stated there are no manufactures that participate in the Federal Medicaid Drug Rebate Program so melatonin does not meet the Centers for Medicare and Medicaid Services (CMS) definition of a "covered outpatient drug" and the State Plan does not allow coverage of sedatives under the over the counter (OTC) benefit. Eric Cannon recommended the state explore options and take the necessary steps to cover melatonin. Sharon Weinstein recommended providing Medication Therapy Management (MTM) education around sleep education to eliminate over prescribing of

less safe therapies. Susan Siegfreid stated that she does not use melatonin frequently in the inpatient setting due to access and coverage. Katherine Thompson and Neal Catalano recommend requiring the use of a USP verified melatonin until better medications are available.

c. **Board Action:** Neal Catalano motioned to approve the prior authorization criteria with recommended changes. Sharon Weinstein seconded the motion. Unanimous approval. Michelle Hofmann was not present for the vote. Eric Cannon recommended adding an update next month regarding the process of getting melatonin approved for coverage. Ngan Huynh stated the Drug Regiment Review Center (DRRC) will present topics for the next few months on insomnia in pediatric and adult patients that will include melatonin.

6. **Meeting Chat Transcript:**
   00:01:04.431,00:01:07.431
   Lisa Angelos, Change Healthcare: Lisa Angelos, Change Healthcare

7. **The next meeting scheduled for Thursday, June 09, 2022** Treatments for insomnia in pediatric patients.

8. **Public Meeting Adjourned:** Neal Catalano motioned to adjourn the meeting. Judith Turner seconded the motion. Unanimous approval. Michelle Hofmann was not present for vote.

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Audio recordings of DUR meetings are available online at:
https://medicaid.utah.gov/pharmacy/drug-utilization-review-board?p=DUR%20Board%20Audio%20Recordings/