Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, June 9, 2022
7:15 a.m. to 8:12 a.m.
Google Meet

Board Members Present:

Eric Cannon, PharmD, FAMCP, Board Chair
Elizabeth Gargaro, MD
Jennifer Brinton, MD
Judith Turner, DVM, PharmD
Katherine Smith, PharmD
Kumar Shah, MSc, PEng
Michelle Hofmann, MD
Neal Catalano, PharmD
Sharon Weinstein, MD
Susan Siegfreid, MD

Board Members Excused:

Kyle Kitchen, PharmD

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

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

University of Utah Drug Regimen Review Center Staff Presenter:

Valerie Gonzales, PharmD U of U DRRC

Other Individuals Present:

Bradley Kalkwarf, Regeneron
Donald Nopper, Apellis
Haley Bruce, Artia Solutions
Lisa Angelos, Change Healthcare
Lovell Robinson, AbbVie
Matthew Call, UUHP
Michael Zarob, Merck
Monet Luloh, PharmD U of U DRRC
Rob Booth, AbbVie
Robert Nohavec, UUHP
Susan Love

Meeting conducted by: Eric Cannon

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Meeting Minutes

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 May Minutes:** Kumar Shah motioned to approve the minutes from May as drafted. Sharon Weinstein seconded the motion. Unanimous approval. Jennifer Brinton was not present for vote.

3. **Housekeeping:** Jennifer Strohecker stated legislation approved funding for two pharmacy related services that will go live July 1, 2022. Program details will be sent out in the Medicaid Information Bulletin (MIB) and posted on the Medicaid website when finalized.

    I. Funding has been approved for 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 educational services face to face. Program enrollment requires members be eighteen years of age or older, have a body mass index (BMI) of twenty-five or greater, and that the member is not currently diagnosed with diabetes mellitus type I or II. CPT code 0403T will be used for billing daily rates and 0488T will be used for billing monthly rates.

    II. Limited funding has been approved for reimbursements to be paid for medication therapy management (MTM) services provided by pharmacists to be delivered to adults and children. Program requires members be Medicaid eligible and enrolled, that the assessment is performed face to face, that the member is not eligible for Medicare part D, and that the member is taking three or more medications to prevent one or more chronic conditions. Comprehensive Medication Management (CMM) tools from the Pharmacy Quality Alliance (PQA) will be used as a guidance for the services. CPT codes 99605, 99606, and 99607 will be used for billing services provided. Documentation

requirements include letters to the members and appropriate providers.

III. The consolidation of the Department of Health and the Department of Human Services into the Division of Integrated Healthcare will be official on July 1, 2022. Physical and behavioral health will be managed under one department. Jennifer Strohecker has been working collaboratively with Brent Kelsey to enhance the Medicaid Program and align with Governor Spencer Cox's One Utah Health Collaborative. Michelle Hofmann stated the pilot program is a value-based healthcare initiative to achieve affordability, equity, and outcomes and will launch the end of June. The program would allow for the transition to a nonprofit 501(c)(3), operated separate from state government while leveraging state-controlled funding. Jennifer Strohecker stated the One Utah Health Collaborative Pledges include: increasing the use of prevention activities within the Medicaid program to achieve better health outcomes, healthcare Integration to ensure all Medicaid members have access to quality physical and behavioral health services through an integrated approach, and shifting Medicaid payment models to compensation based on the quality care provided to Medicaid members rather than relying primarily on quantity of service payments.

4. **P&T Committee Update:** Bryan Larson stated the Pharmacy & Therapeutics Committee met in May and discussed Colony Stimulating Factors for the addition of the new medication class on the Preferred Drug List (PDL).

5. **Treatments for Insomnia in Pediatric Patients:**
    a. **Information:** Valerie Gonzales, PharmD from the University of Utah DRRC presented peer-reviewed research regarding treatment guidelines, indications for use, and safety and efficacy for pediatric insomnia. The National Sleep Foundation defines pediatric insomnia as "repeated difficulty with sleep initiation, duration, consolidation, or quality that occurs despite age-appropriate time and opportunity for sleep and results in some form of daytime functional impairment for

the child and/or family". The International Classification of Sleep Disorders Third Edition (ICSD-3) defines chronic insomnia as persistent symptoms occurring at least three times per week for three or more months. The American Academy of Sleep Medicine Recommendations from 2016 recommend 8-16 hours of sleep depending on age. Recurrent, insufficient sleep in pediatric patients is associated with attention difficulties, impaired learning, behavioral disturbances, poor academic performance, accidents and/or injuries, metabolic disorders, depression, and higher rates of self-harm. There are no medications approved by the Food and Drug Administration (FDA) for pediatric insomnia. Autism Spectrum Disorder (ASD) and Attention Deficit Hyperactivity Disorder (ADHD) are two of the most common pediatric conditions with high burden of sleep disturbances. Insomnia can be diagnosed and treated on its own if other conditions are managed to the best of their ability. Firstline recommendations include behavioral therapy. Dose, timing, and medication formulation adjustments should be considered. The use of melatonin is supported after behavioral therapy has been tried. Side effects of melatonin appear mild and are not known to be associated with serious risks. There are quality concerns regarding over the counter (OTC) dietary supplements due to no pharmaceutical grade Food and Drug Administration (FDA)-approved products in the United States. Diphenhydramine is recommended secondary to melatonin. Alpha-2 receptor agonists can be useful as substitute or adjunctive therapy. There are no formal recommendations supporting the use of sedative medications and orexin antagonists in pediatric patients. Specialist consultation is suggested if failing recommended options to determine the next approach. Utilization data from the previous year shows five pediatric patients aged twelve to seventeen receiving non-benzodiazepine hypnotics.

b. **Board Discussion:** Kumar Shah stated lifestyle changes including exercise, diet, and supplements are probably more useful than medication. Sharon Weinstein stated many patients require pharmacological intervention after behavioral modifications are insufficient. One issue is not having coverage of a melatonin product

available for pediatric use. Elizabeth Gargaro stated there is discrepancies in what is published in treatment guidelines versus current clinical practice. The guidelines do not include trazadone which, according to Dr. Gargaro, is being used after melatonin failure in primary care settings. Eric Cannon agreed. Ngan Huynh stated Medicaid covers diphenhydramine, clonidine, and guanfacine and is currently in the process of developing policy and coverage proposal for melatonin. The melatonin discussion will continue next month for the use in adults. Elizabeth Gargaro stated melatonin coverage is a frequent topic of discussion in clinical practice settings along with what ingredients are contained in the products versus the label. If melatonin is added to the Preferred Drug List (PDL) there can be more oversight of preferred manufacturers and products. Susan Siegfreid stated the May meeting discussion resulted in the recommendation of requiring the use of a USP-verified melatonin.

c. **Board Action:** The melatonin coverage discussion will continue next month after the presentation on treatments for insomnia in adult patients. Ngan Huynh will have additional information on melatonin coverage by other state Medicaid programs and a more refined policy coverage proposal. More guidance is needed to shape policy. Valerie Gonzales suggested considering ConsumerLab in addition to USP-verified products. ConsumerLab follows similar guidelines as USP regarding product impurities and quality assessments. Sharon Weinstein inquired how one would determine appropriate trial and failure without knowing if the patient has received a consistent dose due to consistency of product purity, toxicity, and many dosage formulations.

6. **Intravitreal Implants & Ophthalmic Injections:**
   a. **Information:** Ngan Huynh presented the proposed prior authorization criteria for Intravitreal Implants and Ophthalmic Injections. Medicaid has less than five patients on Ozurdex with no other product utilization.

Criteria for Approval: *All criteria must be met.*

- ❑ Implant or injection is prescribed and administered by an ophthalmologist.
- ❑ Patient is at least 18 years of age (or 12 years of age for Retisert).

Iluvien (fluocinolone acetonide 0.19 mg) Additional Criteria: *All Criteria must be met.*

- ❑ Diagnosis of Diabetic Macular Edema (DME).
- ❑ Previously treated with ophthalmic corticosteroid, without a clinically significant rise in intraocular pressure.
  Medication Used: _____ Duration of Use: _____ Chart Note Page #: _____
- ❑ Previously undergone at least one prior macular laser treatment.
- ❑ Patient does not have any of the following contraindicated conditions:
  - o Glaucoma with a cup to disc ratio of greater than 0.8
  - o Active ocular or periocular infections

Ozurdex (dexamethasone 0.7 mg) Additional Criteria: *All Criteria must be met.*

- ❑ Diagnosis of one of the following:
  - o Diabetic Macular Edema (DME).
  - o Macular Edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).
  - o Non-Infectious Uveitis affecting the posterior segment of the eye.
- ❑ Patient does not have any of the following contraindicated conditions:
  - Glaucoma with a cup to disc ratio of greater than 0.8.
  - Ocular or periocular infections.
  - Torn or ruptured posterior lens capsule.

Retisert (fluocinolone acetonide 0.59 mg) Additional Criteria: *All Criteria must be met.*

- ❑ Diagnosis of Chronic (one year or greater) Non-Infectious Uveitis affecting the posterior segment of the eye.
- ❑ Patient does not have the contraindicated condition "viral, bacterial, mycobacterial and fungal Infections of ocular structures"
- ❑ Tried and failed course of Humira (adalimumab) for at least 6 weeks within last year.
  Details of Failure: _____ Duration of Use: _____ Chart Note Page #: ____

Triesence (triamcinolone acetonide injectable suspension) Additional Criteria: *All Criteria must be met.*

- ❑ Indication for one of the following:
  - o Treatment of the following: sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids
    Topical corticosteroid(s) Used: _____ Duration of Use: _____Chart Note Page #: ____
  - o Visualization during vitrectomy
- ❑ Patient does not have a systemic fungal infection

Xipere (triamcinolone acetonide injectable suspension) Additional Criteria: *All Criteria must be met.*

- ❑ Indication for the treatment of macular edema associated with uveitis
- ❑ Patient does not have ocular or periocular infections

Yutiq (fluocinolone acetonide 0.18 mg) Additional Criteria: *All Criteria must be met.*

- ❑ Diagnosis of Chronic Non-Infectious Uveitis affecting the posterior segment of the eye.
- ❑ Patient does not have the contraindicated condition "ocular or periocular infections"
- ❑ Tried and failed course of Humira (adalimumab) for at least 6 weeks within last year.
  Details of Failure: _____ Duration of Use: _____ Chart Note Page #: ____

Authorization: One implant per approval; injection number to be determined on individual case review.
Reauthorization: Permitted for opposite eye, if treatment of the first eye is successful.

b. **Board Discussion:** Susan Siegfreid recommended changing the title to Ophthalmic Corticosteroid Intravitreal Implants and Injections. Katherine Smith recommended creating a table for the criteria due to inconsistent wording, indication similarities, and repetition.
c. **Board Action:** Ngan Huynh will update the title and create a table for the criteria to bring back for the board to review at the next meeting.

7. **Meeting Chat Transcript:**

00:07:54.376,00:07:57.376
Sharon M Weinstein MD: would someone please send us a link to the policy posting?

00:11:12.159,00:11:15.159
Sharon M Weinstein MD: for the MTM, that was, thank you

00:13:39.134,00:13:42.134
Ngan Huynh: Dr. Weinstein, we haven't yet published the MTM policy. It will soon be published in the July Medicaid Information Bulletins. We will share with you once it is published.

00:14:27.500,00:14:30.500
Michelle Hofmann: Survey about goals, barriers, creative ideas, and priority areas: https://forms.gle/vU34Fu9A29jb1wSs8

00:14:45.171,00:14:48.171
Michelle Hofmann: Submit innovations here: https://forms.gle/WUNoLATQqvNvMup88

00:15:14.595,00:15:17.595
Michelle Hofmann: Questions or to subscribe to newsletter: uthealthcollaborative@leavittpartners.com

00:15:27.817,00:15:30.817
Sharon M Weinstein MD: Thank you!

00:38:21.691,00:38:24.691
Sharon M Weinstein MD: do you see much trazodone use in younger patients?

00:38:33.966,00:38:36.966
Elizabeth Gargaro: absolutely

00:38:41.518,00:38:44.518
Sharon M Weinstein MD: thank you

00:39:53.559,00:39:56.559

Sharon M Weinstein MD: I believe the perception at least in part driving its use is that it is less likely to cause dependency, i.e. compared to benzodiazepines, safer than Z drugs, etc.

00:40:18.223,00:40:21.223
Sharon M Weinstein MD: however, recognize other risks

00:41:38.632,00:41:41.632
Elizabeth Gargaro: I like the ability to limit to USP products

00:43:01.561,00:43:04.561
Michelle Hofmann: Apologies need to drop for another meeting

00:47:51.808,00:47:54.808
Sharon M Weinstein MD: thank you for that discussion

8. **The next meeting scheduled for Thursday, July 14, 2022** Treatments for Insomnia in Adult Patients.

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

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