Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, November 10, 2022
7:15 a.m. to 8:00 a.m.
Google Meet

Board Members Present:

Eric Cannon, PharmD, FAMCP, Board Chair
Jennifer Brinton, MD
Katherine Smith, PharmD
Kumar Shah, MSc, PEng
Kyle Kitchen, PharmD
Michelle Hofmann, MD
Sharon Weinstein, MD
Susan Siegfreid, MD

Board Members Excused:

Judith Turner, DVM, PharmD
Neal Catalano, PharmD

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

Lisa Angelos, PharmD, Pharmacy Director
Bryan Larson, PharmD
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:

Monet Luloh, PharmD U of U DRRC

Other Individuals Present:

Amy Hale, Janssen
Derek Traister, Acadia
Gary Parenteau, Fargo-Moorhead
Heidi Goodrich, Molina Healthcare
Jason Smith, Gilead Sciences
Lindsey Walter, Novartis
Lisa Pulver, Johnson & Johnson
Matthew Call, UUHP
Miles Rooney, Change Healthcare
Natalie Rose, Gilead Sciences
Phil Wettestad, RPh, MBA Novartis
Robert Nohavec, UUHP
San Tran, Genentech
Todd Dickerson, Jazz Pharmaceuticals
Valerie Gonzales, PharmD U of U DRRC

Meeting conducted by: Eric Cannon

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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 and Eric Cannon announced a quorum.

2. **Housekeeping:** Eric Cannon opened nominations for a new Drug Utilization Review Board Chair. Kumar Shah nominated Eric Cannon. Susan Siegfreid seconded the motion. Eric Cannon accepted the nomination to serve as the Drug Utilization Review Board Chair for another year. Sharon Weinstein was not present for vote.

   Ngan Huynh welcomed Lisa Angelos who recently assumed the role of the Utah Medicaid Pharmacy Director. Lisa Angelos' previous experience includes employment with Intermountain Medical Center, The University of Utah College of Pharmacy Drug Regimen Review Center (DRRC), and Change Healthcare.

3. **Review and Approval of September Minutes:** Kumar Shah motioned to approve the minutes from September as drafted. Michelle Hofmann seconded the motion. Unanimous approval. Sharon Weinstein was not present for vote.

4. **P&T Committee Update:** Bryan Larson stated the P&T Committee met in September and discussed Sedative Hypnotics (non-benzodiazepines, non-barbiturates). There were no significant changes made to the drug class. The next meeting will be held in February to discuss Non-stimulants for Attention-deficit/hyperactivity Disorder (ADHD).

5. **CDC Sexually Transmitted Infections Treatment Guidelines, 2021:**
   a. **Information:** Monet Luloh, PharmD from the University of Utah College of Pharmacy Drug Regimen Review Center (DRRC) presented the 2021 Centers for Disease Control and Prevention (CDC) Treatment Guideline Overview for Sexually Transmitted Infections (STIs). Approximately one in five individuals in the United States have a sexually transmitted infection (STI). Nearly half new sexually

transmitted infections occurred among individuals ages fifteen to twenty-four. The most prevalent sexually transmitted bacterial infections include chlamydia, gonorrhea, and pelvic inflammatory disease (PID). The most prevalent sexually transmitted viral infections include human papillomavirus (HPV), and genital herpes (HSV-1 and HSV-2). The most prevalent sexually transmitted parasitic infection is trichomoniasis. Recommended treatment regimens should be used for most patients unless a contraindication exists. Chlamydia is the most reported sexually transmitted bacterial infection in the United States with recommended treatment regimens including oral doxycycline, azithromycin, or erythromycin. Gonorrhea is the second most reported sexually transmitted bacterial infection in the United States with recommended treatment regimens including intramuscular or intravenous ceftriaxone. Presumptive treatment should be provided to all sex partners within the previous 60 days prior to symptom onset or diagnosis of chlamydia or gonorrhea. Pelvic inflammatory disease (PID), an upper reproductive tract infection among women, should be treated with medication regimens that include intramuscular cephalosporin or cephalosporin-like antibiotic in combination with oral doxycycline and metronidazole, depending on disease severity. Some viral sexually transmitted infections (STIs) including human papillomavirus (HPV) and genital herpes (HSV-1 and HSV-2) can be prevented by vaccinations. Anogenital warts may occur months or years after initial inoculation of human papillomavirus (HPV). Recommended patient-administered treatment regimens include Imiquimod cream, Podofilox solution or gel, or Sinecatechins ointment. Recommended physician-administered treatment regimens include cryotherapy with liquid nitrogen, surgical removal, or trichloroacetic or bichloroacetic acid. Herpes simplex virus recommended treatment regimens include oral acyclovir, famciclovir, or valacyclovir. Trichomoniasis recommended treatment regimens include oral metronidazole. Vulvovaginal candidiasis (VVC) is a non-sexually transmitted vaginal infection primarily caused by yeast. Recommended treatment regimens include topical clotrimazole, tioconazole, or butoconazole, intravaginal miconazole or terconazole, or oral fluconazole. At least 1 guideline-

recommended treatments options from the Centers for Disease Control and Prevention (CDC) are preferred on the Utah Medicaid Preferred Drug List (PDL) or have open access with the exception of famciclovir, ivermectin lotion, terconazole, butoconazole, and some over the counter (OTC) options.

b. **Board Discussion:** Eric Cannon inquired if the guidelines included treatment recommendations for partners. Monet Luloh stated the Centers for Disease Control and Prevention (CDC) guidelines included presumptive treatment be provided to all sex partners within the previous 60 days prior to symptom onset or diagnosis of chlamydia or gonorrhea which is the same recommendations sent out by the Department of Health and Human Services (DHHS). Eric Cannon inquired if current coverage is sufficient for all indications without a prior authorization. Bryan Larson stated most options are preferred on the Utah Medicaid Preferred Drug List (PDL) or have open access with the exception to over the counter (OTC) products that do not meet the definition of a covered outpatient drug.

6. **Spravato (esketamine) Prior Authorization:**
   a. **Information:** Ngan Huynh presented approval/denial rates from the previous year and the updated proposed prior authorization criteria for Spravato (esketamine). Out of 482 prior authorizations the approval rate was around sixty-five percent with a denial rate around thirty-five percent.

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

- ❑ Patient is 18 years of age or older.
- ❑ Qualifying diagnosis ***(select diagnosis below)*** managed by or in consultation *(Patient-specific prescriber-to-specialist communication to discuss treatment options)* with a psychiatrist or mental health specialist qualified in the diagnosis and treatment of neuropsychiatric disease *(certified, licensed scope of practice, etc.)* with prescribing authority.
  - Treatment-Resistant Depression (TRD). **OR**
  - Depressive symptoms observed with Major Depressive Disorder (MDD) with acute suicidal ideation or behavior.
- ❑ Baseline depression assessment score utilizing a validated depression rating scale (scale name, score):

  _____
- ❑ Failure of two antidepressants from at least two different classes at up to maximally indicated doses but no less than the commonly recognized minimum therapeutic doses, each used for ≥ 6 weeks, unless clinically significant adverse effects are experienced or all are contraindicated (e.g., selective serotonin reuptake inhibitor [SSRI], serotonin-norepinephrine reuptake inhibitor [SNRI], tricyclic antidepressant [TCA], bupropion, mirtazapine); Failure of two of the following antidepressant augmentation therapies, each used for ≥ 4 weeks, unless clinically significant adverse effects are experience or all are contraindicated: second generation antipsychotic, lithium, thyroid hormone, buspirone:

  Medication and dose: _____ Medication and dose: _____
  Dates of use: _____ Dates of use: _____
  Result: _____ Result: _____
- ❑ Used in conjunction with an oral antidepressant at up to maximally indicated doses but no less than the commonly recognized minimum therapeutic doses: Medication, dose, dates: _____
- ❑ Plan to monitor and manage "black box" warnings of sedation, disassociation, abuse/misuse, and suicidal thoughts or behaviors.
- ❑ Plan to administer in healthcare setting, under supervision of a health care provider, observe patient for at least 2 hours after administration and advise no driving or use of heavy machinery for the remainder of the day.

Requested doses: *Medicaid approves specific doses and quantities of medications. Please indicate specific dose:*

Treatment-Resistant Depression (TRD)					
Induction Phase			Maintenance Phase		
	First Dose	Second Dose		Dosing Frequency	Continued Dose
Week 1	*Starting Day 1 Dose:* 56mg	☐ 56 mg OR ☐ 84 mg	Weeks 5 – 8	☐ once weekly	☐ 56 mg OR ☐ 84 mg
Week 2	☐ 56 mg OR ☐ 84 mg	☐ 56 mg OR ☐ 84 mg			
Week 3	☐ 56 mg OR ☐ 84 mg	☐ 56 mg OR ☐ 84 mg	Week 9 and after	☐ once weekly OR ☐ every 2 weeks	☐ 56 mg OR ☐ 84 mg
Week 4	☐ 56 mg OR ☐ 84 mg	☐ 56 mg OR ☐ 84 mg			

Major Depressive Disorder (MDD) with acute suicidal ideation or behavior	
☐ 84 mg twice per week for 4 weeks	☐ 56 mg twice per week for 4 weeks (based on tolerability)

Re-authorization Criteria for TRD (all must be included or met):

- ❑ Updated letter of medical necessity or updated chart notes demonstrating positive clinical response.
- ❑ Updated depression assessment score utilizing the same validated depression rating scale (scale name, score):

  _____
- ❑ Re-evaluation by or in consultation (Patient-specific prescriber-to-specialist communication to discuss treatment options) with a psychiatrist or mental health specialist qualified in the diagnosis and treatment of neuropsychiatric disease *(certified, licensed scope of practice, etc.)* with prescribing authority.
- ❑ Used in conjunction with an oral antidepressant at up to maximally indicated doses but no less than the commonly recognized minimum therapeutic doses: Medication, dose, dates: _____
- ❑ Requested dosing: _____

Authorization:

- ***Depressive symptoms observed with MDD with acute suicidal ideation or behavior*** – Up to one (1) month
- ***Treatment-Resistant Depression*** - Up to three (3) months

Re-authorization for TRD: Up to six (6) months

b. **Board Discussion:** Eric Cannon inquired what the main denial reason was. Ngan Huynh stated the most common reason for denial was not meeting the clinical criteria of trial and failure of two antidepressants at the maximum indicated doses or for not having sufficient documentation submitted after outreach was completed. Eric Cannon inquired if ketamine injections are covered. Susan Siegfreid stated ketamine infusions are frequently used off-label for the treatment of chronic pain as well as for major depressive disorder. Bryan Larson stated ketamine injections do not require a prior authorization through medical coverage so it would be hard to determine if the injections were being used on or off label. Susan Siegfreid suggested adding the REMS enrollment requirements to the prior authorization criteria and having a stronger statement about no driving after receiving Spravato (esketamine). Katherine Smith suggested changing the word “advise” to “require” no driving and advise no use of heavy machinery for the reminder of the day and to let the provider figure out how to enforce the criteria.

c. **Board Action:** Kumar Shah motioned to approve the prior authorization criteria with the proposed changes. Katherine Smith seconded the motion. Unanimous approval. Eric Cannon requested prior authorization criteria be sent to the board members for review prior to the meeting.

7. **Meeting Chat Transcript:**
   00:43:27.419,00:43:30.419
   Sharon M Weinstein MD: please mark my participation, sorry for being late, thank you, Dr Weinstein.

8. **The next meeting scheduled for Thursday, December 08, 2022** Auvelity (dextromethorphan/bupropion).

9. **Public Meeting Adjourned:** Katherine Smith motioned to adjourn the meeting. Kumar Shah seconded the motion. Unanimous approval.

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