Utah Department of Health & Human Services

Drug Utilization Review Board

Meeting Minutes

Thursday, December 8, 2022
7:15 a.m. to 7:40 a.m.
Google Meet

Board Members Present:

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

Board Members Excused:

Judith Turner, DVM, PharmD
Katherine Smith, PharmD
Kumar Shah, MSc, PEng

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

Andrea Rico, CPhT, CPC
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:

Aimee Redhair, Biogen
Amy Hale, Janssen
Chris, Bristol Myers Squibb
Gary Parenteau, Fargo-Moorhead
Heidi Goodrich, Molina Healthcare
Jason Bott, Eli Lilly
Jason Smith, Gilead Sciences
Joanne LaFleur, PharmD U of U DRRC
John Schillo, Lundbeck
Kendrick LaFleur, Odyssey House
Lisa Hafker
Luna Adamo, PharmD Biogen
Matthew Call, UUHP
Matthew Metcalf, CSL Vifor
Michael Zarob, Merck
Miles Rooney, Change Healthcare
Monet Luloh, PharmD U of U DRRC
Natalie Rose, Gilead Sciences
Robert Booth, AbbVie
Robert Nohavec, UUHP
San Tran, Genentech

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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. Eric Cannon announced a quorum.

2. Review and Approval of November Minutes: Susan Siegfreid requested updating her statement "ketamine injections are frequently used for the treatment of chronic pain as well as off label for major depressive disorder" to "ketamine infusions are frequently used off-label for the treatment of chronic pain as well as for major depressive disorder". Sharon Weinstein motioned to approve the minutes from November with the recommended changes. Neal Catalano seconded the motion. Unanimous approval. Michelle Hofmann was not present for vote.

3. Auvelity (dextromethorphan/bupropion):
    a. Information: Valerie Gonzales, PharmD from the University of Utah College of Pharmacy Drug Regimen Review Center (DRRC) presented peer-reviewed research regarding indications for use, safety and efficacy, treatment guidelines, and considerations for prior authorization criteria for Auvelity (dextromethorphan/bupropion). The treatment of depression is an area of high unmet medical need. Response rate for first-line antidepressants including selective serotonin reuptake inhibitors (SSRIs) and serotonin and norepinephrine reuptake inhibitors (SNRIs) is forty to sixty percent in naïve patients with only thirty to forty-five percent of patients achieving remission. Relapse rates are high within six months of remission. Auvelity (dextromethorphan/bupropion) is the first oral N-methyl-D-aspartate (NMDA) antagonist approved for the treatment of major depressive disorder (MDD) in adults. Recommended dosages range from one tablet daily to one tablet twice daily, depending on renal function and metabolism. Prior to initiation of Auvelity (dextromethorphan/bupropion) providers should screen for history of bipolar disorder, mania, or hypomania (like other antidepressants),

blood pressure, and ensure that the patient is not receiving any other bupropion or dextromethorphan containing agents. Clinical practice guidelines have not been updated since the approval of Auvelity (dextromethorphan/bupropion). First-line therapy recommendations for the treatment of major depressive disorder (MDD) include second generation antidepressants, psychotherapy, or a combination of pharmacotherapy with psychotherapy. The NICE guideline (2022) included any antidepressant, if indicated, could be used first line for moderate to severe depression. The choice of therapy should be based on the patient's clinical profile. The pivotal clinical trials Phase 2 Ascend and Phase 3 Gemini included adults with a DSM-5 diagnostic criteria for major depressive disorder and a Montgomery-Asberg Depression Rating Scale (MADRS) score of at least twenty-five. This pivotal trial excluded patients with prior failure of two or more antidepressants, psychotic features, significant risk of suicide, and substance abuse in the prior year. Auvelity (dextromethorphan/bupropion) outperformed placebo in the Phase 3 Gemini trial. Auvelity (dextromethorphan/bupropion) outperformed bupropion monotherapy in the Phase 2 Ascend trial. The unpublished STRIDE-1 trial failed to meet the primary endpoint for the reduction in the Montgomery-Asberg Depression Rating Scale (MADRS) score at week six although the primary endpoint tended to favor Auvelity (dextromethorphan/bupropion). Dizziness was the most common adverse reaction with Auvelity (dextromethorphan/bupropion). Auvelity (dextromethorphan/bupropion) contains a Black Box Warning that antidepressants may increase the risk of suicidal thoughts/behaviors in pediatric and young adult populations. Use during pregnancy is not recommended. Auvelity (dextromethorphan/bupropion) has not yet been scheduled as a controlled substance and may pose a risk for patients with substance abuse history or abuse history of dextromethorphan containing antitussives. Considerations for prior authorization criteria include requiring age and indication for use according to labeled indication, requirement of step therapy with a trial and failure of a selective serotonin reuptake inhibitor (SSRI) or serotonin and norepinephrine reuptake inhibitor (SNRI), and provider attestations for appropriate

use and abuse risk.

b. Board Discussion: Ngan Huynh, PharmD presented utilization data for Auvelity (dextromethorphan/bupropion). There have been zero claims or utilization for Auvelity (dextromethorphan/bupropion. Four prior authorization requests have been received and denied for Auvelity (dextromethorphan/bupropion) due to the manufacturer not participating in the Federal Medicaid Drug Rebate Program therefore the drug does not meet the Centers for Medicare and Medicaid Services (CMS) definition of a "covered outpatient drug" and is not eligible for coverage. The manufacturer would need to enroll in the Federal Medicaid Drug Rebate Program to be eligible for coverage by Medicaid. Kyle Kitchen inquired if Auvelity (dextromethorphan/bupropion) had a similar or better response rate compared to selective serotonin reuptake inhibitors (SSRIs) or serotonin and norepinephrine reuptake inhibitors (SNRIs). Valerie Gonzales stated no direct comparisons to selective serotonin reuptake inhibitors (SSRIs) or serotonin and norepinephrine reuptake inhibitors (SNRIs) were included in the studies. Auvelity (dextromethorphan/bupropion) outperformed buproprion monotherapy. The response rates were sixty percent at week six with remission rates around forty percent depending on the study. Kyle Kitchen suggested not having strict prior authorization criteria if Auvelity (dextromethorphan/bupropion) is shown to have significant potential over selective serotonin reuptake inhibitors (SSRIs), or serotonin and norepinephrine reuptake inhibitors (SNRIs).

4. The next meeting scheduled for Thursday, January 12, 2023 Topic TBD.

5. Public Meeting Adjourned: Susan Siegfreid motioned to adjourn the meeting. Sharon Weinstein 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/