**AHCCCS**

**Pharmacy and Therapeutics Committee Written Public Testimony**

June 18 , 2024

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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | I am a pediatric pulmonologist who is part of a team at Phoenix Children's Hospital caring for approximately 550 children and adults with cystic fibrosis in Arizona. Inhaled anti-pseudomonal antibiotics that treat pseudomonas aeruginosa infection in our patients are one of the more challenging medications for our patients to get access to in a timely manner and have required a great deal of work on behalf of our pharmacy team to get coverage for these medications. Initiating treatment in a timely manner may increase the likelihood of eradicating pseudomonas aeruginosa infection and preventing chronic infection and the associated increase in pulmonary infections and progressive lung damage that can occur once a chronic pseudomonas aeruginosa infection is established. Choosing the most appropriate treatment option for each patient depends on individual patient factors such as age, culture sensitivities and previous intolerance to medications. I would like to request that CF patients with evidence of pseudomonas infection on respiratory culture, have equal access to all available inhaled antibiotics to ensure that they receive the most appropriate therapy in a timely manner. Delaying appropriate treatment of pseudomonas aeruginosa infection for our patients can result in pulmonary exacerbation, hospitalization, decreased quality of life, patient and/or parent anxiety and an increased likelihood of chronic infection with pseudomonas aeruginosa which requires ongoing treatment. |
| Drug/Product: | All Inhaled anti-pseudomonal antibiotics including inhaled tobramycin and inhaled aztreonam. |
| Therapeutic Drug Class: | Inhaled antibiotics |
| Testimony Format: | Written |

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| --- | --- |
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| Please check the box of the statement that best applies.: | I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| If yes, name organizations and roles:: | Teva pharmaceuticals |
| Summary of Testimony: | As an ACT registered nurse, I have personally observed the benefits of this medication (Uzedy). We have patients on our team that are struggling with treatment resistance, frequent hospitalization, as well as medication non-adherence. I have witnessed patients that have been switched to Uzedy to have improved stabilization from their previous long-acting injection, as well as better outcomes. I have not seen any adverse reactions/side effects from the use of Uzedy to date. I feel increased access of this medication could possibly benefit more patients that have yet to have a chance to utilize it. The obstacle to being able to easily prescribe this medication could absolutely delay a possible new option for those SMI patients that are struggling with treatment resistance. |
| Drug/Product: | Uzedy (long-acting injection) |
| Therapeutic Drug Class: | antipsychotic |
| Testimony Format: | Written |

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| --- | --- |
| Name: | Monica Benavidez D.O. |
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| Please check the box of the statement that best applies.: | I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| If yes, name organizations and roles:: | I am currently an ACT psychiatrist at Terros 23rd ave clinic. |
| Summary of Testimony: | Uzedy (risperidone LAI) is a great option for our patients with schizophrenia. We know that at least 2/3 of our patients with schizophrenia struggle with adherence and that leads to a decline in the health of our patients. Those that decompensate end up hospitalized and incarcerated. Uzedy is different because it gets to therapeutic levels with one injection, by 8 to 24 hours. It requires no 2nd loading dose or oral supplementation. Long acting injectables are preferred for all my patients to help keep them well. This would be a great addition to the formulary without the PA that slows down the initiation of treatment. Pts have done very well on Uzedy and tolerate it very well. |
| Drug/Product: | Uzedy LAI |
| Therapeutic Drug Class: | Atypical Antipsychotic (LAI) |
| Testimony Format: | Written |

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| --- | --- |
| Name: | Lori Parker PMHNP-BC |
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| If yes, name organizations and roles:: | TERROS Heatlth Staff PMHNP Best Outcome Psychiatry- private practice |
| Summary of Testimony: | It is unfair to the patient when they are forced to try other medications in the same class when one medication such as Lybalvi is best indicated from the beginning such as those with significant psychotic symptoms with high riskf of weight gain and/or metabolic syndrome. |
| Drug/Product: | Lybalvi |
| Therapeutic Drug Class: | Second generation antipsychotic |
| Testimony Format: | Written |

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| --- | --- |
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| Summary of Testimony: | I have personally been prescribing lybalvi for the past 12 extensively, and now see not only the positive symptom improvement, but improvement in terms of metabolic concerns and managing side effects associated with olanzapine. We are seeing positive results, and a noticeable decrease in side effects and wish to see this become more available and on formularies. Thanks! |
| Drug/Product: | Lybalvi |
| Therapeutic Drug Class: | atypical antipsychotics |
| Testimony Format: | Written |

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| --- | --- |
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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | As a healthcare provider, I am incredibly impressed with the effectiveness of Lybalvi in treating psychiatric disorders such as schizophrenia and bipolar I disorder, and I am particularly struck by the lower dosage required to achieve desired therapeutic results.  Lybalvi is an atypical antipsychotic that combines olanzapine and samidorphan. This combination is designed to provide the well-documented efficacy of olanzapine, while samidorphan works to mitigate the metabolic side effects often associated with antipsychotic treatment.  While Lybalvi effectively manages psychotic symptoms and decreases metabolic risk factors, the most notable benefit in my experience is the potency of the medication. Remarkably, smaller dosages of Lybalvi have been sufficient to achieve the same therapeutic effect as larger doses of other antipsychotic medications. This not only potentially reduces side effects, but also makes the prescription more cost-effective for the patient.  Another major advantage of Lybalvi is its impact on weight management. Many antipsychotics are associated with weight gain, but with Lybalvi, I have observed a decrease in weight gain, and in some cases, weight loss in patients. This has greatly improved the quality of life for my patients and has likely contributed to the higher rate of compliance observed with Lybalvi.  In conclusion, Lybalvi's ability to provide effective treatment with smaller dosages represents a significant development in the management of psychiatric disorders. It is a medication that addresses the typical challenges faced with antipsychotic medications, and I would highly recommend considering it as a potential treatment option. |
| Drug/Product: | Lybalvi |
| Therapeutic Drug Class: | Antipsychotic |
| Testimony Format: | Written |

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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | I have been a Pediatric Endocrinologist in clinical practice since 1992. This last 18 months have been very challenging for my patients with growth hormone deficiency due to the shortage of daily growth hormone. Many patients have had interruption of their medical regimen and have not grown well due to missing weeks of growth hormone therapy. During this time, my office staff has had to complete multiple prior authorizations in an attempt to find medication for our patients. During this time frame, weekly growth hormone therapy has arrived on the market (currently 3 companies which make weekly growth hormone products). Our patients with private insurance were able to take advantage of the weekly growth hormone products to bridge the gaps in daily growth hormone. However, our patients with AHCCCS insurance were unable to use the weekly growth hormone products. There is also a huge convenience factor is being able to receive a weekly injection rather than a daily injection. This is especially important for our patient who live in two households. Many of our children with growth hormone deficiency also have a significant needle phobia and seem to do much better with a weekly injection. I feel it is very important to add at least one weekly growth hormone product to the AHCCCS formulary. My preference would be for Skytrofa. The data with this medication demonstrates a superior growth velocity compared to those patients on a daily injection (most likely due to better compliance). |
| Drug/Product: | Skytrofa Sogroya Ngenla  These 3 products are a weekly growth hormone injection approved for use in children with growth hormone deficiency. My interpretation of the data demonstrates that Skytrofa has an increase in growth velocity compared to daily injection. |
| Therapeutic Drug Class: | Growth hormone (Somatropin) |
| Testimony Format: | Written |

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| Please check the box of the statement that best applies.: | I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| If yes, name organizations and roles:: | Mannkind Territory Business Manager |
| Summary of Testimony: | Request equal access to all insulin for patients. Request formulary coverage so providers can choose what best fits their patients’ needs. |
| Drug/Product: | Afrezza/Cartridge (oral inhalation) |
| Therapeutic Drug Class: | Hypoglycemics, Insulin and Related Agents |
| Testimony Format: | Written |

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| Summary of Testimony: | I am advocating the potential inclusion of Afrezza, an ultra-rapid-acting inhaled insulin, in the Arizona Health Care Cost Containment System (AHCCCS) formulary. Afrezza offers unique advantages that can complement existing diabetes management strategies. Afrezza is a unique insulin formulation that is inhaled, providing a more convenient and less invasive method of insulin administration compared to subcutaneous injections. Its ultra-rapid onset of action allows for better postprandial glucose control and less nocturnal hypoglycemia, which can greatly improve the quality of life for patients with diabetes. Furthermore, Afrezza's unique pharmacokinetic profile mimics the natural insulin response to meals more closely than injectable insulins, which could potentially lead to improved glycemic control and fewer hypoglycemic events. This can directly reduce the burden of disease management for our patients and indirectly decrease healthcare costs associated with managing hypoglycemia and other diabetes-related complications. Inclusion of Afrezza in the AHCCCS formulary would provide patients and healthcare providers with an additional tool in diabetes management, promoting patient-centered care and personalized treatment strategies. We believe that patient choice is a fundamental aspect of healthcare, and having Afrezza as an option would empower our patients to participate more actively in their own care. Given these advantages, the inclusion of Afrezza in the AHCCCS formulary could provide a valuable option for patients and healthcare providers, enhancing personalized diabetes care. |
| Drug/Product: | Afrezza Cartridge (inhalation) |
| Therapeutic Drug Class: | Hypoglycemics, Insulin and related agents |
| Testimony Format: | Written |

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| Name: | EDGARDO R LAUREL MD |
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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | Subject: Request for Inclusion of Ozempic (Semaglutide) in the Insurance Formulary for Chronic Kidney Disease  To whom it may concern,  I am writing to express my strong support for the inclusion of Ozempic (Semaglutide) in the insurance formulary for patients with chronic kidney disease (CKD). As a healthcare professional, I believe that providing access to this medication is crucial for managing CKD effectively and improving patient outcomes. 1. Clinical Efficacy: \* Ozempic, a glucagon-like peptide-1 (GLP-1) receptor agonist, has demonstrated significant benefits in patients with type 2 diabetes and CKD. \* Clinical trials have shown that Ozempic reduces HbA1c levels, promotes weight loss, and lowers cardiovascular risk factors in this patient population. \* Importantly, Ozempic has also been associated with renal benefits, including a reduction in albuminuria and preservation of kidney function. \* On March 5, the top-line results of the FLOW trial were released from this pivotal kidney outcomes trial: Use of semaglutide in patients with diabetic kidney disease reduced the primary outcome—a composite of kidney failure, 50% decline in estimated glomerular filtration rate (eGFR), and cardiovascular (CV) or kidney death—by an impressive 24%. \* How many patients with CKD want to lose a few pounds and benefit from better glycemic and/or blood pressure control? Yes, all of them. 2. Unmet Need: \* CKD is a prevalent and serious condition affecting millions of Americans. \* Current treatment options for CKD are limited, and patients often struggle to achieve glycemic control while managing other comorbidities. \* Ozempic offers a novel approach by addressing both glycemic control and renal protection. 3. Cost-Effectiveness: \* While Ozempic may have a higher upfront cost, its long-term benefits can lead to reduced hospitalizations, dialysis, and other costly complications associated with CKD. \* Investing in preventive measures now can yield substantial savings in the future. 4. Patient Well-Being: \* CKD significantly impacts patients’ quality of life, leading to fatigue, fluid retention, and other symptoms. \* By including Ozempic in the formulary, we can empower patients to better manage their condition and improve their overall well-being.  Semaglutide is going to "remake" much more than chronic kidney disease but will have a huge impact on cardiology (CVD), endocrinology (DM), orthopedic surgery (weight related joint disease) , hepatology (fatty liver), on and on and on.  What I wanted to convey is that cards, endo, and nephro have all been attacking the same metabolic derangement. This drug fixed it better than any previous drug.  I am already seeing amazing effects from these medications. I have a steady stream of patients on semaglutide who are coming in 10 to 20 pounds lighter, with blood pressure so much better that I am stopping (some of) their blood pressure medications. They are also reducing or stopping their insulin.  Semaglutide is on the verge of remaking CKD. This remarkable drug seems to correct the metabolic derangements that are driving our CKD epidemic. If we can actually get this drug into our patients, we are going to see an even more profound reduction in the epidemiology of CKD that was kick-started by RAS inhibitors 2 decades ago and amplified by flozination in the last few years.  In light of the above points, I urge you to consider adding Ozempic to the insurance formulary for CKD. Doing so would enhance patient care, reduce complications, and align with evidence-based practice. Thank you for your attention to this matter. I trust that you will make a decision that prioritizes the well-being of our patients.  Sincerely,  Edgardo R. Laurel, MD Arizona Kidney Disease Nephrologist AKDHC-Thomas   2545 E Thomas Rd Ste 120   Phoenix AZ 85016   (602) 419-3378 |
| Drug/Product: | Ozempic- Semaglutide |
| Therapeutic Drug Class: | Incretin-GLP1RA |
| Testimony Format: | Written |

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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | To whom it may concern,  I am requesting you to reconsider coverage for opzelura. Currently, this medication is very difficult to get covered and patients would benefit from having this alternative as a steroid sparing medication. |
| Drug/Product: | Opzelura |
| Therapeutic Drug Class: | Immunomodulators, Atopic Dermatitis |
| Testimony Format: | Written |

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| Name: | Heather O'Connell |
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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | I am requesting that Opzelura be included as a preferred medication for Medicaid patients for atopic dermatitis. In my experience, Opzelura is highly effective with minimal side effects. As you know, patients that are good candidates for Opzelura are often required to try and fail alternative non-steroidal medications first. Unfortunately, the alternative non-steroidal topical medications such as Eucrisa, Tacrolimus, and Elidel are less effective often with more frequent side effects such as itching, burning, stinging, or photosensitivity. Additionally, these alternative step-therapy options each require prior authorizations only to fail to treat the atopic dermatitis effectively. Requiring a patient try and fail two topical medications that each require a prior auth significantly delays care for a patient and may result in poor health outcomes including psychiatric effects from suffering with atopic dermatitis. Thank you for your consideration. |
| Drug/Product: | Opzelura |
| Therapeutic Drug Class: | Immunomodulator, Atopic dermatitis |
| Testimony Format: | Written |

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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | Opzelura is effective for the management of moderate atopic dermatitis for pts who faile topical steroid and non steroidal (other) therapies but who are poor candidates or who want to avoid long term systemic management. It is also very effective in the treatment of refractory Vitiligo. Pts would benefit from access to drug therapy. |
| Drug/Product: | Opzelura |
| Therapeutic Drug Class: | Topical Jak inhibitor |
| Testimony Format: | Written |

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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | Hello,  My name is Lauren Weidman PA-C. I work at Omni Dermatology in Tempe, Arizona & have a high percentage of medicaid patients in my practice. I believe Opzelura should be covered after a single step due to the efficacy of the medication. Many of patients go through months and months of trying and failing multiple topicals (steroids, calcineurin inhibitors, Eucrisa, etc.) before finding improvement with Opzelura. It would be so helpful for my patients to be able to have Opzelura as an option early on in their treatment regimen to help improve their comfort levels (itchiness due to atopic dermatitis), appearance of rashes & decrease risk of superimposed infections from scratching at the skin. Additionally, would decrease their risk of side effects from long-term steroid use (atrophy, telangiectasias, etc.)  Thank you for your time and consideration!  Lauren Weidman PA-C |
| Drug/Product: | Opzelura |
| Therapeutic Drug Class: | Immunomodulators, Atopic Dermatitis |
| Testimony Format: | Written |

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| --- | --- |
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| If yes, name organizations and roles:: | Community Medical Services, medical provider for OTP facility |
| Summary of Testimony: | I believe Brixadi should be a formulary option and should not require a step up from sublocade. Many patients I am seeing prefer long acting injectables over suboxone due drug adherence as well sustained blood levels but prefer a smaller needle and sublocade for many patients is not an option due to needle size because of needle phobia due to prior IV drug use. |
| Drug/Product: | Brixadi |
| Therapeutic Drug Class: | long acting injectible treating opiate use disorder |
| Testimony Format: | Written |

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| Please check the box of the statement that best applies.: | I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| Summary of Testimony: | More than 100,000 people die in the US annually. Fentanyl is contaminating the drug supply the majority of deaths are accidental and unintentional overdose. |
| Drug/Product: | Brixadi, weekly and monthly. We need more options for individualized dosing. Needs to be on formulary to improve access for those in need. |
| Therapeutic Drug Class: | Opioid partial agonist. Long acting injectable weekly and monthly buprenorphine. |
| Testimony Format: | Written |

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| Summary of Testimony: | I am the medical director of addiction medicine for Community Bridges Inc. I am not writing representing CBI, only as a licensed physician in AZ that exclusively and extensively treats addiction. I interact with many physicians and nurse practitioners within our organization. We treat addiction and specifically substance use disorders regularly. Medications for Opioid Use Disorder are a vital pharmacotherapy with proven mortality benefits. (~50% mortality reduction after maintained on treatment after non-fatal overdose).  Increasing access to all forms of buprenorphine is why I am writing. Sublingual formulations of buprenorphine have been the mainstay of treatment for OUD on the market since early 2000s. This was when prescription opioids and heroin were the main forms of opioids in a diagnosis of an OUD. Now that the illicit drug supply has changed to fentanyl, the pharmacokinetics of this molecule when used illicitly have made it more difficult for patients to initiate treatment in the traditional dosing regimens of buprenorphine. This was one of the reasons which prompted a new avenue to have a different type of delivery and maintenance of buprenorphine with the extended release (XR) formulations that are administered subcutaneously and last for 28 days. The first was XR was Sublocade. The clinical indications for this medication should be for anyone with moderate or severe opioid use disorder who have initiated treatment with transmucosal buprenorphine for at least 7 days. No matter if they are in active opioid use or sustained remission. Arizona placed other parameters on AHCCCS approval of Sublocade that are restrictive for patients to receive life saving medication. Some patients cannot initiate or tolerate the sublingual formulation due to the longer elimination times of fentanyl and nor-fentanyl. Some patients cannot initiate or maintain sublingual because of their environment (med gets stolen, start using again and stop their buprenorphine). Limitations or restrictions for patients taking a sublingual medication, cause an increase risk of overdose and mortality. Sublocade is a great medication for any patient that cannot sustain taking sublingual longer than 7 days and for those that are on long term maintenance treatment for OUD that don't want to take a sublingual formulation anymore. Sublocade has a wonderful role for patients in Arizona, and just like many medications, it has limitations. It is 2 month loading dose scenario of 300mg, 300mg then maintenance of 100mg. This dosing is the same for all patients that may not be ideal. It may be too much of a concentration for some patients taking 16mg SL daily or less. And it may not be enough for patients taking 24mg SL daily. Sublocade is beneficial, yet another medication might be more ideal for a large population of patients in Arizona.  A new formulation of buprenorphine that has many studies supporting its superiority and preference from that of Sublocade is, Brixadi. Brixadi is a form of XR buprenorphine injectable that has up to 4 different dose equivalencies to the sublingual form. It also has weekly and monthly durations. This formulation would be an incredible addition to the already growing addiction treatment formulary, to make MOUD more accessible for our patients, decrease the risk of recurrence of opioid use and essentially, to lower mortality and address this opioid epidemic in Arizona. And especially to those in my patient population. Weekly injection or monthly injection of Brixadi can be administered after only a single dose of a sublingual formulation of buprenorphine. Thus, decreasing the time making patients susceptible to increased risk of overdose and mortality. Brixadi treatment can help avoid a prolonged or severe precipitated withdrawal when utilized in acute care settings such as withdrawal "detox" facilities, emergency departments, hospitals and of course, clinics with trained addiction specialists. The physical injection administration is much more comfortable based on patient preference compared to Sublocade.  The most recent ASAM conference in 2024 has been presenting research that strengthens the consensus that injectable long acting buprenorphine be offered to all patients as part of their stabilization plan and/or long term maintenance of their pharmacotherapy for OUD. Brixadi is one of those long acting formulations that I would strongly recommend as the mainstay of treatment for my patient populations. Brixadi would not be meant to replace the existing formulations. It is a very favorable option that should be added to the formulary in addition to all other buprenoprhine products. MOUD saves lives and I truly feel that long acting buprenorphine in weekly and monthly injections (like Brixadi) will save more lives by stabilizing OUD even more effectively than before, so our AHCCCS patients have a chance at life and health. The means are available with this type of buprenorphine product and I strongly recommend that it become accessible to our patients by being on the AHCCCS formulary.  1) Effect of Buprenorphine Weekly Depot (CAM2038) and Hydromorphone Blockade in Individuals With Opioid Use Disorder A Randomized Clinical Trial Sharon L. Walsh, PhD; Sandra D. Comer, PhD; Michelle R. Lofwall, MD; Bradley Vince, DO; Naama Levy-Cooperman, PhD; Debra Kelsh, MD; Marion A. Coe, BA; Jermaine D. Jones, PhD; Paul A. Nuzzo, MA; Fredrik Tiberg, PhD; Behshad Sheldon, BS; Sonnie Kim, PharmD. 2) Weekly and Monthly Subcutaneous Buprenorphine Depot Formulations vs Daily Sublingual Buprenorphine With Naloxone for Treatment of Opioid Use Disorder A Randomized Clinical Trial Michelle R. Lofwall, MD; Sharon L. Walsh, PhD; Edward V. Nunes, MD; Genie L. Bailey, MD; Stacey C. Sigmon, PhD; Kyle M. Kampman, MD; Michael Frost, MD; Fredrik Tiberg, PhD; Margareta Linden, PhD; Behshad Sheldon, BS; Sonia Oosman, BS; Stefan Peterson, PhD; Michael Chen, PhD; Sonnie Kim, PharmD 3) Long-term safety of a weekly and monthly subcutaneous buprenorphine depot (CAM2038) in the treatment of adult out-patients with opioid use disorder Michael Frost1, Genie L. Bailey2,3, Nicholas Lintzeris4,5, John Strang6 , Adrian Dunlop7,8,Edward V. Nunes9 , Jakob Billeskov Jansen10, Lars Chemnitz Frey11, Bernd Weber12, Paul Haber13,14, Sonia Oosman15, Sonnie Kim15 & Fredrik Tiberg16. 4) Incidence of Precipitated Withdrawal During a Multisite Emergency Department–Initiated Buprenorphine Clinical Trial in the Era of Fentanyl Gail D’Onofrio, MD, MS; Kathryn F. Hawk, MD, MHS; Jeanmarie Perrone, MD; Sharon L. Walsh, PhD; Michelle R. Lofwall, MD; David A. Fiellin, MD; Andrew Herring, MD |
| Drug/Product: | Brixadi |
| Therapeutic Drug Class: | Medication for Opioid Use Disorder Addiction "MAT" |
| Testimony Format: | Written |

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| Please check the box of the statement that best applies.: | I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee. |
| If yes, name organizations and roles:: | I am Medical Manager (in Medical Affairs) for Supernus. My role is providing updated clinical/medical information to providers, work with clinical investigators in trial design and participation, support national accounts in P&T/DUR hearings, review labeling change proposals, and respond to Medical Information Requests from FDA/Practitioners. |
| Summary of Testimony: | Present recently published and poster data (2023-2024) supporting Qelbree's efficacy and safety for use in ADHD. (1) Head to head comparison between Atomexetine to Qelbree- showing Qelbree statistically significant efficacy and safety compared to Artomexetine: (Price.Maxwell,-Extended-release Viloxazine compared with Atomexetine for ADHD: CNS drugs (2023) 1-6) (2) Open Label Extension Data (up to 1 year) supporting Qelbree's safety, efficacy, and patient adherence (Poster presentation at NEI and APSARD conference) (3) Overview of Qelbree cardiac safety data and long-term risk of cardiovascular disease with stimulants and atomexetine (Le Zhang et al. AADHD disorder Medications long term risk of CVD- JAMA Psychiatry) |
| Drug/Product: | Qelbree (Viloxazine ER) (a non-stimulant for the treatment of adult and pediatric ADHD) |
| Therapeutic Drug Class: | Stimulants and Related Agents |
| Testimony Format: | Oral, Written |