P&T Written Testimony
May 21, 2025

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Organization(s) and role(s): null
Testimony: As a pharmacist dedicated to optimizing patient outcomes, I strongly advocate for the inclusion of Cobenfy in the formulary. Cobenfy represents a groundbreaking advancement in the treatment of mental health disorders due to its novel mechanism of action. Unlike traditional therapies, it does not interact with the D2 receptor, eliminating many of the burdensome side effects commonly associated with older treatments, such as weight gain, movement disorders, and sexual dysfunction. The absence of these adverse effects is a crucial factor in improving adherence and long-term outcomes for patients. Many individuals discontinue or avoid treatment due to these well-documented side effects, leading to disease progression, relapse, and increased healthcare costs. By offering Cobenfy as a first-line option, we can ensure that patients receive effective treatment without the need for trial and error with older, less tolerable medications. Furthermore, prioritizing Cobenfy on the formulary aligns with modern standards of care, emphasizing patient safety, tolerability, and improved quality of life. Failing to provide access to this medication means continuing to expose patients to treatments with known and significant drawbacks. For these reasons, I strongly urge the formulary committee to approve coverage of Cobenfy, ensuring that patients receive the most innovative and well-tolerated treatment option available.
Drug/Product: Cobenfy
Therapeutics Drug Class: Muscarinic

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Organization(s) and role(s): Teva
Testimony: To Whom it May Concern: I hope this letter finds you well. As a nurse dedicated to providing the best possible care to my patients, I am always on the lookout for medications that offer effective outcomes while maintaining a manageable profile for those in my care. I am writing to share my thoughts on Uzedy, a medication I was introduced to while working at an IOP servicing a significant population of Schizophrenics. I have recently come to appreciate for its potential in improving the health and well-being of my patients. Uzedy, as a treatment option, has proven to be an excellent choice for patients in need of stabilizing,

treating, and maintaining their symptom. I have found that Uzedy offers several advantages that are particularly beneficial to my patient population: 1. Issues with medication compliance – Since Uzedy is a long-acting injection, with administration in either 1 or 2 month options, patients and practitioners can have more confidence that the medications is remaining at a therapeutic level. Also, being a subcutaneous injection I find patients are far more receptive to this type of LAI, as there are less reports of discomfort then using intramuscular injections. 2. As a registered nurse I have personally observed improvements in patients with debilitating symptoms have significant better quality of life with the use of Uzedy after long periods of treatment resistance from similar treatments/medications. 3. Patient adherence to receiving this injection appears to give more of my patients hope, where they had lost it. They see the improvements, they become excited about the chance to become more independent and live a better life (more independent with living situations, maybe even getting closer to stable employment opportunities) and because of this they begin to participate with more effort in their plan of care. 4. Side effects seem to be, in some cases, even less than the oral administration. I'm not sure if it is related to possible poor compliance with oral medications or if Uzedy is just more effective than oral risperidone, but I personally have seen my patients experience less hospitalizations to inpatient psych facilities while routinely on Uzedy. I believe that incorporating Uzedy into my patients' treatment plans has not only provided them with effective symptom management, but it has also promoted a better overall experience with their healthcare. Uzedy addresses a critical need in our clinical practice, offering better outcomes and more convenience for our patients. When patients have better control and symptom management As a healthcare professional, I am committed to using the most effective and patient-friendly treatments available. Given the promising results I have seen with Uzedy, I will continue to advocate for its inclusion in the treatment regimens of my patients who would benefit from it. Thank you for taking the time to consider my perspective on Uzedy as a treatment option. If you have any further questions or would like to discuss my experiences with this medication in more detail, please do not hesitate to reach out. Casey Hollingsworth, RN-MSN, 702-**521-0237**
Drug/Product: Uzedy
Therapeutics Drug Class: long acting injection - psych

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Organization(s) and role(s): null
Testimony: It is with great joy to see and follow patients and their families relieved and enjoying symptoms remission thanks to long acting injectable antipsychotics. It is a primordial need to have all that medications class approved and available in preferred formulary.
Drug/Product: All long acting injectable antipsychotics
Therapeutics Drug Class: long acting injectable antipsychotics

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Organization(s) and role(s): Teva Pharmaceuticals
Testimony: Encourage parity in coverage and access for long-acting injectable medications for the treatment of schizophrenia. – **see attached letter pdf**
Drug/Product: Long-Acting Injectables
Therapeutics Drug Class: Antipsychotics

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Organization(s) and role(s): null
Testimony: I have been pushing for lumateperone/ Caplyta to be on the AHCCCS formulary since it came out. This is finally a medication that is approved by the FDA for Bipolar II. The only other medication indicated for this is harsh and not as effective. Patients need an alternative except only one medication. Caplyta is very effective, and I have patients who have paid out of pocket for it because it is so helpful.
Drug/Product: lumateperone Caplyta
Therapeutics Drug Class: antipsychotic

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Organization(s) and role(s): null
Testimony: I am writing to request the inclusion of semaglutide (Ozempic) in your formulary for patients with type 2 diabetes and chronic kidney disease (CKD), based on compelling evidence from the FLOW trial, a phase 3b randomized, placebo-controlled study. The FLOW trial, conducted across 28 countries with 3,533 participants, demonstrated that once-weekly subcutaneous semaglutide (1.0 mg) significantly improves kidney and cardiovascular outcomes in patients with type 2 diabetes and CKD. Specifically, the trial showed a

24% reduction in the risk of major kidney disease events, defined as the onset of kidney failure (dialysis, transplantation, or eGFR <15 mL/min/1.73 m²), a sustained ≥50% reduction in eGFR, or death from kidney-related or cardiovascular causes, compared to placebo (hazard ratio 0.76, 95% CI 0.66–0.88). Additionally, semaglutide reduced the risk of major cardiovascular events by 18% and all-cause mortality by 20%. The trial also reported a slower decline in eGFR (1.16 mL/min/1.73 m²/year less than placebo), indicating a protective effect on kidney function. These outcomes are particularly significant given the high burden of CKD in patients with type 2 diabetes, affecting approximately 40% of this population, and its association with increased risks of kidney failure, cardiovascular events, and mortality. Current treatment options often fail to adequately address these risks, leaving a critical unmet need. Semaglutide's demonstrated efficacy, combined with a favorable safety profile (fewer serious adverse events than placebo, 49.6% vs. 53.8%), positions it as a valuable addition to standard care for this high-risk group. Including semaglutide in your formulary would provide patients with access to a therapy that not only improves glycemic control but also offers substantial kidney and cardiovascular protection, potentially reducing long-term healthcare costs associated with dialysis, hospitalizations, and cardiovascular complications. I urge you to consider the FLOW trial's robust evidence and the urgent needs of patients with diabetic CKD when updating your formulary. Thank you for your attention to this matter. I am happy to provide additional information or discuss this request further. Please contact me at [your phone number] or [your email address]. Sincerely, Edgardo Laurel, MD
Drug/Product: Ozempic
Therapeutics Drug Class: Incretin mimetic-enhancers

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Organization(s) and role(s): null
Testimony: Would like to see access to cobenfy made easier
Drug/Product: Cobenfy
Therapeutics Drug Class: Muscarinic

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Organization(s) and role(s): null

Testimony: I am writing in support of inclusion of diroximel fumarate to the formulary for patients with multiple sclerosis on AHCCCS insurance. While diroximel fumarate has a similar mechanism of action to dimethyl fumerate which is already on the formulary, phase 3 clinical trials prove that diroximel fumerate has lower rates of side effects. Having less side effects can help patients stay on their medication more consistently which is important for their long term care. I can confirm as a clinician specializing in the care of multiple sclerosis that there is a clinical reason to use diroximel fumerate in patients with multiple sclerosis.
Drug/Product: diroximel fumerate
Therapeutics Drug Class: Fumerates: multiple sclerosis disease modifying therapies

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Organization(s) and role(s): TG therapeutics- Speaker
Testimony: I believe that our MS patients, with the help of their providers, should be able to choose among the different medications in the CD19/20 depleting category
Drug/Product: Briumvi
Therapeutics Drug Class: ANTI CD20 b cell depleting medication for MS

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Organization(s) and role(s): null
Testimony: I am writing this testimony in support for Multiple Sclerosis Drug, Vumerity, to be included in the Preferred Drug List as, First Line with no Step Therapy, as : 1. Clinical studies have shown that Vumerity provides consistent and reliable efficacious results, making it a preferred choice 2. Its signi□ant advantage is its tolerability. Patients often experience fewer side effects compared to those taking generic options, which leads to better adherence to the medication regimen, ultimately improving patient outcomes 3. Vumerity offers a more convenient dosing schedule 4. Backed by a robust support from the manufacturer, including patient assistance programs and educational resources. These support systems are invaluable in helping patients navigate their treatment journey In summary, Vumerity stands out for its efficacy, tolerability, convenient dosing with strong manufacturer support for the patients. I believe that these benefits make it a superior choice over generic alternatives and can greatly enhance the quality of care we provide to our

patients Thank you for your attention. If you have any questions or would like to discuss this further, please feel free to reach out .Best regards Naveed Vehra, MD
Drug/Product: Vumerity
Therapeutics Drug Class: Multiple Sclerosis

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Organization(s) and role(s): null
Testimony: As part of a peds endocrine practice, we want all forms of glucagon to be available with no restrictions that require a PA to give families choice for what they feel is safest for their situation. This also saves time for office staff who have to obtain PAs for medications the providers and families feel better serve the patient due to safety and ease of use/storage. GVoke's shelf life is 24 months and can be used down to age 2 which makes it very flexible for most of our patient population.
Drug/Product: GVoke hypopen 0.5mg and 1mg doses
Therapeutics Drug Class: Glycogenolytics

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Organization(s) and role(s): null
Testimony: Of over 9500 antipsychotic prior authorization claims filed, less than 42% were approved affecting the lives and families of many patients in Arizona. AHCCCS requiring 3 failures on a preferred agent before a patient can get the medicine that their doctor thinks is best for them is the same as requiring a patient to suffer with psychosis, for a year. (Three months on a failed agent, one month taper x 3 = 1 year.) This is not humane. As a person who has had to live through years of failed treatments, finding the one that works is life-altering. Being able to return to full-time employment after years of isolation is life-altering. Humane treatment including shared decision making between patient and provider is life-altering. Requiring prolonged suffering for access to treatment, is life-ending.
Drug/Product: antipsychotic medications
Therapeutics Drug Class: antipsychotics/neuroleptics

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Organization(s) and role(s): Teva, VEO (employee)
Testimony: Lauren Prole asked me to submit a written testimony through this form, as I am only approved to give verbal testimony for one product (I selected Uzedy for verbal testimony and written testimony for all other products). I submitted a summary previously, and I am submitting written testimony for Austedo, Simlandi, Selarsdi, and Ajovy via written testimony. I will provide verbal testimony for Uzedy during the meeting. Please see below for written testimonies. AJOVY Hi, my name is Mandeep. I'm a pharmacist with Teva in medical affairs. I'm here to provide testimony for AJOVY (fremanezumab-vfrm). AJOVY is a CGRP antagonist that is indicated for the preventive treatment of migraine in adult patients. AJOVY is the only long-acting, self-administered, subcutaneous anti-CGRP with the option of monthly or quarterly dosing, allowing it to be dosed as few as four times per year, either with the auto-injector or the pre-filled syringe. AJOVY is contraindicated in patients with serious hypersensitivity to fremanezumab or to any of the excipients. In clinical trials, the most common adverse reactions were injection site reactions. For complete information, please refer to the full AJOVY prescribing information. On March 11, 2024 The American Headache Society published a position statement update in Headache: The Journal of Head and Face Pain, regarding therapies targeting calcitonin gene-related peptide (CGRP) for the prevention of migraine. The AHS position update states that CGRP targeting therapies should be considered as first line therapy for migraine prevention along with previous first-line treatment options without a requirement for prior failure of other classes of preventative migraine treatments. The Board of Directors of The American Headache Society base this conclusion on a review and discussion of randomized placebo-controlled clinical trials, post hoc analyses, open-label extensions of these trials, and prospective and retrospective observational studies regarding migraine preventative therapies. The HALO clinical trial program included two multicenter, randomized, 12-week, double-blind, placebo-controlled studies and provided the pivotal data presented in the prescribing information. Patients treated with AJOVY achieved statistically significant reductions in monthly migraine days (EM) and headache days of at least moderate severity (CM) after accounting for placebo effect (EM: 1.3+0.6 quarterly and 1.5+0.6 monthly; CM 1.8+0.3 quarterly; 2.1+0.3 monthly). Efficacy was maintained in subjects on stable doses of concomitant preventive medication in the pivotal and long term study phases. In a post-hoc analysis of long-term clinical trial data, wearing-off was not observed during quarterly or monthly dosing arms. AJOVY-dependent reduction in weekly migraine days was maintained or increased over 15 months, demonstrating consistency of efficacy over time. AJOVY has shown significant efficacy in both clinical and real world studies, long term studies, EM and CM populations, patients with comorbidities, patients on other preventive migraine medications, patients previously unresponsive to migraine preventive medications, and has been shown to reduce acute medication use, healthcare resource utilization and costs. In light of these data, we at Teva respectfully ask the members of the committee to make AJOVY available to patients within Arizona Medicaid. Thank you. SIMLANDI Hi, my name is Mandeep. I'm a pharmacist with Teva in medical affairs. I'm here to provide testimony for SIMLANDI (adalimumab-ryvk). SIMLANDI is a high-concentration, citrate-free interchangeable biosimilar to Humira (adalimumab) which launched in May 2024. SIMLANDI is the first and only biosimilar to be interchangeable with the high-concentration 40 mg/0.4 mL formulation of Humira, and has exclusivity on this until May 20, 2025. SIMLANDI 40 mg/0.4 mL is interchangeable for the indications of use, dosage forms, and routes of administration described in the Prescribing Information. Per the FDA, an interchangeable biosimilar may be substituted at the pharmacy

without intervention by the prescriber. This is subject to state pharmacy laws. SIMLANDI was initially approved as a 40 mg/0.4 mL autoinjector with a press-on skin mechanism. The SIMLANDI autoinjector has received the Arthritis Foundation “Ease of Use” certification. SIMLANDI 80 mg/0.8 mL autoinjector and SIMLANDI prefilled syringes (80 mg/0.8 mL, 40 mg/0.4 mL, and 20 mg/0.2 mL) are also approved. SIMLANDI is a tumor necrosis factor (TNF) blocker approved to treat ALL reference product indications with the exception of pediatric UC, HS, and Uveitis, which are currently protected under exclusivity. A phase III switching study was conducted in 567 patients with moderate to severe plaque psoriasis. Patients were randomized to switch back and forth from SIMLANDI and EU-Humira then SIMLANDI, or stay on EU-Humira continuously without switching through week 28. This was followed by an optional open-label extension on SIMLANDI until week 52. There were no significant differences between the switching and non-switching cohorts for PK, efficacy, safety, and immunogenicity. PK parameters fell within predetermined equivalence thresholds between switching and non-switching groups. The mean percent PASI improvement was similar in the switching group (96.0%) and the non-switching group (95.8%). Changes in DLQI score, sPGA, and “clear” or “almost clear” sPGA from baseline to week 28 were similar between switching and non-switching groups. The percentage of patients with adverse events was similar in the switching and non-switching groups, with the most commonly reported TEAE of ISR reported in 2.5% of switching and 5.5% of non-switching groups. A real-life SIMLANDI autoinjector patient handling experience open-label study among 107 patients with moderate to severe rheumatoid arthritis was conducted through week 8, followed by a 48-week optional extension phase with PFS. There was a 100% successful injection rate reported by patients and study sites at week 8. No handling events with AI were noted. Approximately 80% of patients felt the AI ‘very easy’ to use. Improvements were seen with efficacy endpoints (ACR20/50/70, SDAI, DAS28, HAQ scores). No unexpected safety signals were observed, and no local ISRs were reported. SIMLANDI, like other TNF-inhibitors, has a BOXED WARNING for serious infections and malignancy. I will refer you to the prescribing information for complete safety information. We at Teva respectfully thank the members of the committee for SIMLANDI’s preferred status within Arizona Medicaid. Thank you. SELARSDI Hi, my name is Mandeep. I'm a pharmacist with Teva in medical affairs. I’m here to provide testimony for SELARSDI (ustekinumab-aekn). SELARSDI is a biosimilar to Stelara (ustekinumab). SELARSDI is approved in the following presentations: 90 mg and 45 mg pre-filled syringes for subcutaneous use, which launched on February 21, 2025; a 130 mg/26 mL vial used for the intravenous induction doses for Crohn’s disease and ulcerative colitis, which launched on April 7,2025; a 45 mg vial for subcutaneous use is also approved and has an upcoming expected launch. The FDA reviewed the application for SELARSDI interchangeability with Stelara and has waived the requirements to complete a separate interchangeability/switching study. SELARSDI has received provisional determination of interchangeability by the FDA. Teva and Alvotech anticipate interchangeability to be available for SELARSDI starting in May 2025, after Amgen’s first interchangeable exclusivity period for Wezlana ends on April 30, 2025. SELARSDI is an interleukin (IL)-12 and IL-23 antagonist approved to treat all of the indications covered by reference product Stelara including the following: Adult and pediatric patients 6 years and older with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy; adult and pediatric patients 6 years and older with active psoriatic arthritis (PsA); adults with moderately to severely active Crohn’s disease (CD); adults with moderately to severely active ulcerative colitis (UC). A phase III, multicenter, double-blind, 52-week study was conducted in 581 patients with moderate to severe chronic plaque psoriasis to compare the efficacy, safety, tolerability, and PK between patients treated with SELARSDI and EU-Stelara. Patients were randomized 1:2 to SELARSDI or EU-Stelara respectively. A 45 mg or 90 mg subcutaneous injection was given on week 1 and week 4, then every 12 weeks at week 16, 28, and 40. At week 16, patients initially randomized to the SELARSDI group continued to receive SELARSDI, while patients in the EU-Stelara group were re-randomized 1:1 to either continue to EU-Stelara or switch to SELARSDI. The last evaluation and end of study occurred on week 52. The primary endpoint of Psoriasis Area Severity Index (PASI) percent improvement from baseline to week 12 was 87.3% for SELARSDI and 86.8% in EU-Stelara, which were within therapeutic equivalence parameters of 90% CI within ±10%, in accordance with FDA criteria. From baseline to Week 52, the percentage improvement in PASI was comparable between patients who switched from EU-Stelara to SELARSDI and those who continued on previous treatments (SELARSDI/SELARSDI or EU-Stelara/EU-Stelara). Findings corroborate the persistence of efficacy despite

treatment switching at week 16. Up until week 16, 34.5% of patients in the SELARSI arm and 33.6% of patients in the EU-Stelara arm reported TEAEs. Safety profiles remained largely unchanged and similar between the treatment arms after switching at week 16. Most of the TEAEs were mild to moderate in severity and were considered unrelated to the treatment assignment. No serious TEAEs, TEAEs that caused study discontinuation, or deaths were reported throughout the entire study. At week 16, 25.4% of patients in the SELARSDI arm and 48.2% of patients in the EU-Stelara arm had positive ADAs. At end of study, 21.2% of patients in the SELARSDI/SELARSDI arm, 31.5% of patients in the EU-Stelara/SELARSDI arm, and 26.7% of patients in the EU-Stelara/ EU-Stelara arm had positive ADAs. The numerical differences in ADA and NAb frequencies had no clinically meaningful impact on the study treatments' efficacy, safety, or PK profiles. We at Teva respectfully ask the members of the committee to make SELARSDI available to patients within Arizona Medicaid as a preferred drug. Thank you. AUSTEDO Hi, my name is Mandeep. I'm a pharmacist with Teva in medical affairs. I am here to discuss Austedo/Austedo XR, which contain deutetrabenazine, a VMAT2 inhibitor indicated for TD and HD chorea, both of which are chronic, hyperkinetic movement disorders. Austedo was studied in the AIM-TD, ARM-TD, and FIRST-HD trials for the TD and HD chorea indications, respectively. Eligible patients were then able to enroll in the open-label extension studies. Two 3 year long-term OLE studies RIM-TD and ARC-HD showed no new safety signals and long term tolerability of Austedo. I will emphasize that patients had continued AIMs score improvements in RIM-TD while maintaining a stable dose. Patients in RIM-TD had a mean total motor AIMs score of 10.7 for items 1-7.1 The current Austedo PA criteria requires that the patient has an AIMS score of 3 or 4, which corresponds to moderate and severe movements, respectively, on any one of the AIMS items 1-9. According to this criterion, a patient could have a total motor AIMs score of 14 for items 1-7 and be denied Austedo. The average patient in the RIM-TD study, with an AIMs score of 10.7, would also be denied Austedo based on current PA criteria despite having high disease burden. Furthermore, AIMS item 8 is a global judgment that is associated with inconsistent interpretation and variable clinical application. The mean baseline AIMS item 8 score was 2.6 in RIM-TD meaning the average RIM-TD patient would also be denied Austedo. Secondly, the current PA criteria already requires a diagnosis of moderate to severe TD, which is redundant with the minimum AIMs score criterion of 3 or 4 for items 1-9. The APA recommends that patients who have moderate to severe or disabling TD associated with antipsychotic therapy be treated with a reversible inhibitor of VMAT2. The criteria denies Austedo to patients with disabling TD, which is not aligned with APA guidelines. As you're likely aware, the Unified Huntington's Disease Rating Scale, UHDRS, is a research tool used to assess HD. This scale is copyrighted & intellectual property of the Huntington Study Group and requires licensing agreement and fees. The UHDRS is used by neurologists involved in HD research. However, many community neurologists aren't trained and don't use the UHDRS in routine clinical practice. Yet, the criteria requires a UHDRS score ranging from 1 to 4 on any one of UHDRS chorea items 1 through 7. My request to the committee is three-fold. Firstly, I respectfully ask the members of the committee to consider adding language to the PA criteria, so patients with disabling TD may access Austedo. Secondly, I respectfully ask the committee to consider amending or removing the requirement for a minimum AIMs score for patients with high disease burden. Thirdly, I request the committee remove the criterion requiring a UHDRS score, as it is a research tool and is not required for any other PDL VMAT2 inhibitor. Thank you.
Drug/Product: Austedo, Simlandi, Selarsdi, Ajovy, and Uzedy (oral/verbal)
Therapeutics Drug Class: Movement Disorders, CYTOKINE & CAM ANTAGONIST AGENTS, ANTIPSYCHOTICS - SECOND GENERATION - ATYPICAL LONG ACTING INJECTABLES, CALCITONIN GENE-RELATED PEPTIDE (CGRP) RECEPTOR ANTAGONIST

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Organization(s) and role(s): null
Testimony: I am writing to provide an overview of the cost-effectiveness of Ozempic (semaglutide 1 mg) in comparison to Trulicity (dulaglutide) and SGLT-2 inhibitors for the management of type 2 diabetes mellitus (T2DM). Clinical Efficacy and Cost-Effectiveness: Recent studies have demonstrated that once-weekly semaglutide 1 mg is associated with greater reductions in HbA1c and body weight compared to dulaglutide. Specifically, semaglutide 1 mg was found to be more cost-effective than dulaglutide 3 mg and 4.5 mg, with improved quality-adjusted life expectancy and, in some comparisons, lower direct costs due to reduced incidence of diabetes-related complications. When compared to SGLT-2 inhibitors, such as empagliflozin 25 mg, semaglutide 1 mg has shown to be cost-effective, offering increased life expectancy and quality-adjusted life years (QALYs). Although semaglutide has higher acquisition costs, these are partially offset by the avoidance of diabetes-related complications, leading to acceptable incremental cost-effectiveness ratios (ICERs). Cost Considerations: According to a pharmacoeconomic review in the UK, the average annual drug cost for semaglutide 1 mg is approximately $2,544, while dulaglutide's annual cost is around $2,194. Despite the higher drug cost, semaglutide's superior efficacy may lead to overall cost savings by reducing the need for additional treatments and managing complications more effectively. The cost of pharmaceuticals to pharmacy benefit managers in the US is proprietary and unpublished. Conclusion: In summary, semaglutide 1 mg offers a favorable balance between clinical benefits and cost, making it a cost-effective option for T2DM management compared to both dulaglutide and SGLT-2 inhibitors. Its ability to improve glycemic control and reduce complications can lead to long-term healthcare savings, justifying its use despite higher upfront medication costs. Citations: 1. The long-term cost-effectiveness of once-weekly semaglutide 1 mg vs dulaglutide 3 mg and 4.5 mg in the UK. PubMed Central 2. Evaluating the Cost-Effectiveness of Once-Weekly Semaglutide 1 mg Versus Empagliflozin 25 mg for the Treatment of Patients with Type 2 Diabetes Mellitus in the UK. SpringerLink, 3. Cost of Achieving HbA1c Treatment Targets and Weight Loss Responses with Once-Weekly Semaglutide Versus Dulaglutide in the United States.
Drug/Product: Semaglutide
Therapeutics Drug Class: GLP-1

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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.
Organization(s) and role(s): null
Testimony: Supporting Access to Prescribed Mental Health Medications As someone who lives with a mental health condition and takes a prescribed stimulant, I know firsthand how important access to the right medication can be. I've also seen how essential antipsychotic medications are through the experience of a close friend who relies on them for stability and wellness. These medications can be life-changing—and sometimes life-saving. That's why I believe strongly that decisions about psychiatric medication should remain between a patient and their healthcare provider, without unnecessary barriers or delays. Every

person's experience with mental illness is different, and so is their response to treatment. What works for one individual may not work for another. We need to ensure that physicians and their clients have the freedom to choose the treatment that's most effective for them, without being forced to try and fail on alternatives that don't meet their needs. Removing access barriers isn't just about efficiency—it's about dignity, safety, and recovery. I urge you to support policies that protect individualized care and uphold the right to timely access to prescribed mental health medications. Thank you for your time and commitment to mental health.
Drug/Product: Stimulants and Antipsychotic Medications
Therapeutics Drug Class: Stimulants and Antipsychotic Medications

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Organization(s) and role(s): null
Testimony: Please consider long-acting (weekly) GH as the first alternative when daily GH fails. Daily GH are all very similar. If one fails , for any variety of reasons, so will the 2nd; so this switch to a different daily formulation is not a needed step and will waste time and money.
Drug/Product: Any weekly long-acting GH formulation (there are several)
Therapeutics Drug Class: Growth hormone, weekly

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Organization(s) and role(s): null
Testimony: It works and for many parents it is a game changer because the day starts off on the right foot!
Drug/Product: Jornay PM
Therapeutics Drug Class: ADHD medication

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Organization(s) and role(s): null
Testimony: It is my understanding that AHCCCS policy currently requires children with growth hormone deficiency (GHD) to step through two short acting growth hormone (hGH) products before they are allowed to utilize a long-acting hGH. There is an adherence burden when comparing daily hGH vs. long-acting (weekly) hGH, as taking doses once daily is more challenging, painful, and logistically complicated vs. once weekly. Furthermore, there is clinical data supporting improved growth outcomes using once weekly Skytrofa in comparison to daily hGH. It is my opinion that requiring patients to try two different daily hGH products before being allowed access to a long-acting hGH product is no longer clinically appropriate, given the available clinical data and my growing clinical experience with Skytrofa and other long-acting hGH products. I request amending the current hGH treatment policy to either a single step or no step requirement before proceeding with a long-acting hGH.
Drug/Product: Skytrofa
Therapeutics Drug Class: hGH (somatropin), long-acting

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Organization(s) and role(s): null
Testimony: I have used and prescribed medication for schizophrenia and feel this medication will change the longevity and quality of life for people
Drug/Product: Cobenfy
Therapeutics Drug Class: Muscarinic Agonist

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Organization(s) and role(s): null

Testimony: I would like to see this medication as a first line treatment option for my patients with SMI. There are multiple benefits to the side effect profiles that are medications are not able to offer. Improves compliance when patients do not have weight gain, EPS, or cause elevations in prolactin.
Drug/Product: Cobenfy
Therapeutics Drug Class: antipsychotic

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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.
Organization(s) and role(s): AstraZeneca - Clinical Account Director and Employee
Testimony: AIRSUPRA- • The information I will discuss is provided to support the addition of Airsupra as a short-acting rescue therapy for patients with Asthma for patients in the Arizona Medicaid program under the category of Glucocorticoids, Inhaled without the requirement of prior ICS/LABA (Symbicort, Dulera or Advair) therapy. Overview of AIRSUPRA iNDICATION • AIRSUPRA is a fixed-dose combination rescue inhaler containing albuterol (a short acting beta2-agonist or SABA) and budesonide (an inhaled corticosteroid or ICS). It indicated for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma aged 18 years and older. AIRSUPRA is the only rescue agent available in the US indicated to reduce risk of exacerbations. Overview of Asthma and Unmet Medical Need • Inhaled SABA has historically been the treatment of choice for rapid relief of acute asthma symptoms. However, high use of SABA alone for relief of asthma symptoms may worsen inflammation and increase the risk of exacerbations and asthma-related costs. - Recommendations from global and national guidelines have re-examined rescue therapy for this reason. • Both the Global Initiative for Asthma or GINA have recommendations for an ICS/SABA Reliever. • Recommendations stress the importance of treating the symptoms and inflammation of asthma, and provide recommendations for rescue therapy as a part of the overall treatment regimen. GINA does not recommend treatment with SABA monotherapy. The most recent update in 2024 recommends concomitant use of as-needed SABA and ICS (in separate or combination devices) across all steps of maintenance. There are several aspects to keep in mind when reviewing GINA 2024 • FIRST - AIRSUPRA is intended to be used as a rescue therapy of acute symptoms, alone or on top of other ICS/LABA MAINTENANCE therapies such as Symbicort or Dulera in the United States. • Second - The GINA recommendations for the use of the ICS/formoterol (a ICS/LABA) inhaler as rescue are primarily based on clinical data using a budesonide/formoterol DPI which is a different formulation, with different dosing which is not approved and not available in the US. ¬Given this, the doses used in the clinical studies that support the use of ICS/formoterol for rescue in these recommendations may not be achieved with the pMDI formulations available in the US. • Lastly, I would like to call to the committee's attention the FDA approved package insert for Symbicort (budesonide & formoterol) & Dulera (mometasone & formoterol) states under IMPORTANT LIMITATIONS: that each is not TO BE USED for the relief of acute bronchospasm. Closing Statement As a reminder, AIRSUPRA is a rescue therapy and is not indicated for maintenance treatment; therefore, it would fall under the same category as other SABAs used for rescue therapy SUCH AS ALBUTEROL. Based on today's testimony, AstraZeneca requests that AIRSUPRA be available for patients with Asthma in the Arizona Medicaid program under the category of Glucocorticoids, Inhaled without the requirement of prior Symbicort, Dulera or Advair therapy. FASENRA- • The information I will discuss is provided to support the maintenance of FASENRA on the preferred drug list on the ARIZONA Medicaid

Program. Indication, Usage and Dosage: • FASENRA's indicated AS add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype. (1.1) • treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). • FASENRA is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus Please refer to the FASENRA Prescribing Information for complete product information including Warnings and Precautions. FASENRA Overview and Distinguishing Characteristics: • FASENRA is the only biologic approved for Asthma maintenance dosed subcutaneously once every 8 weeks after the first 3 doses administered every 4 weeks. • For EGPA, FASENRA is administered subcutaneously as a single 30mg injection once every 4 weeks. • FASENRA is the only respiratory biologic that offers 2 administration options PFS or AutoInjector. Additionally, it offers Q8W dosing for asthma (the fewest number of maintenance doses per year) and every 4 weeks for EGPA. Safety Results for Pivotal Primary Trials • The most common adverse reactions in the Ph 3 pivotal trials for Asthma occurring with ≥3% incidence in the FASENRA vs. placebo groups included headache (8% vs. 6%), pyrexia (3% vs. 2%), pharyngitis (5% vs. 3%) and hypersensitivity reactions (3% vs. 3%). • In adult patients with EGPA. The incidence of adverse reactions were consistent to those reported in asthma, with the exception of headache, which occurred in 17% of FASENRA-treated patients with EGPA. No new adverse reactions were identified. We respectfully request that Fasenra remain on the Arizona Medicaid PDL as an option for patients with severe eosinophilic asthma or EGPA. I would be happy to answer and questions at this time.
Drug/Product: Airsupra and Fasenra
Therapeutics Drug Class: Immunologics: Immunomodulators, Asthma and Glucocorticoids, Inhaled

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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.
Organization(s) and role(s): null
Testimony: The ACT Coalition represents patients with chronic conditions, including mental health. We are requesting improved access to oral atypical antipsychotics. There are currently 3 failures on a preferred agent for person with bi-polar disorder. This is very harmful for someone already struggling with their mental health. AHCCCS Mental Health Medication Utilization Report January 2025 report to the legislature shows of the more than 9,500 antipsychotic prior authorization claims filed in Arizona in 2023, only about 42% of claims were approved. Persons with serious mental illness struggle to take these medicines that are critical for their stability, we should not be making it even more difficult by not giving them access to the medicines their doctor believes is best for them. We are asking AHCCCS to improve access to these medicines by reducing the steps required to one preferred agent.
Drug/Product: N/A
Therapeutics Drug Class: Antipsychotics

Arizona P&T Meeting (May 21, 2025)
Public Comment: CRENESSITY (crinecerfont)
Neurocrine Biosciences

Clinical Summary Points:

- Introduction and P&T Request (page 1, paragraph 1-2)
- Disease State Overview for CAH (page 1, paragraph 4-5)
- Clinical Trial Summary for Adult and Pediatric Populations (page 1-2, paragraph 6-8)
- Important Safety Information (page 2, paragraph 9-10)
- Summary and Closing Remarks (page 2, paragraph 10)

CRENESSITY (crinecerfont) is the first and only non-steroidal therapy that was studied as part of the largest interventional clinical development program for CAH patients and is now FDA-approved as the first novel treatment option for CAH patients in over 70 years.

We respectfully request that the committee allow access to CRENESSITY for classic CAH patients in the State of Arizona utilizing appropriate criteria aligned to the FDA label, and as such, reflecting CRENESSITY's demonstrated ability to be used as adjunctive treatment to glucocorticoid (GC) replacement to control the patient's androgen levels OR improve their daily GC requirements to a more physiological dose.

CRENESSITY is indicated as adjunctive treatment to GC replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).

CAH is a rare genetic disorder impacting the adrenal glands, resulting in patients not producing enough cortisol leading to excessive systemic circulation of ACTH & overproduction of adrenal androgens. The excess levels of adrenal androgens result in patients with CAH experiencing advanced bone age, early puberty, short adult stature, decreased fertility in both males and females, and mental health issues such as depression and anxiety. CAH is life-long and life-threatening with patients experiencing an average of 11 hospitalizations over a lifetime due to an increased risk of adrenal crises due to the lack of endogenous cortisol production.

Traditional therapy includes high doses of GCs, which are higher than what is typically needed to replace deficient cortisol. This reduces excess levels of androgens in some patients but can also be associated with a number of short- and long-term complications.

The efficacy of CRENESSITY were evaluated in two randomized, double-blind, placebo-controlled Phase 3 studies that included 182 adults and 103 pediatric subjects (4 to 17 years of age) with classic CAH. In both pivotal studies, CRENESSITY demonstrated a statistically significant difference compared to placebo and met its primary and key secondary endpoints.

In the 24-week adult study, for the primary endpoint, participants in the CRENESSITY group demonstrated a statistically significant -27% reduction in total GC daily dose compared to a -10% reduction in the placebo group ($p<0.0001$). For the key secondary endpoint evaluating the

change from baseline in serum A4 at week 4, while GC doses remained stable, the least square mean difference (LSMD) at Week 4 was -345 ng/dL ($p<0.0001$).

In the 28-week pediatric study, participants in the CRENESSITY group demonstrated a statistically significant difference compared to the placebo group for the primary endpoint evaluating the change from baseline in serum A4, at week 4 while GC doses remained stable. The LSMD at Week 4 was -268 ng/dL ($p=0.0002$). For the key secondary endpoint evaluated at Week 28, the CRENESSITY group demonstrated a statistically significant -18% reduction in total GC daily dose compared to a 6% increase in the placebo group ($p<0.0001$).

The safety of CRENESSITY in adults and pediatric patients was evaluated in two Phase 3 randomized, double-blind, placebo-controlled studies. In adults, the most common adverse reactions (at least 4% for CRENESSITY and greater than placebo) were fatigue, headache, dizziness, arthralgia, back pain, decreased appetite, and myalgia. In pediatric patients, the most common adverse reactions (at least 4% for CRENESSITY and greater than placebo) were headache, abdominal pain, fatigue, nasal congestion, and epistaxis.

Warnings and precautions for CRENESSITY include hypersensitivity reactions to CRENESSITY and risk of acute adrenal insufficiency or adrenal crisis with inadequate concomitant GC therapy. For additional important safety information, please refer to the Full Prescribing Information.

In summary, CRENESSITY (crinecerfont) is a first-in-class adjunctive treatment option for both adults and pediatric patients aged (4 years of age and older) with classic CAH. As part of the largest interventional clinical development program and first novel treatment option for patients with classic CAH in over 70 years, CRENESSITY achieved both primary and key secondary endpoints demonstrating ACTH-mediated adrenal androgen control while enabling patients to reduce their daily GC doses to a more physiological dose.

References:

Auchus RJ, et al. N Engl J Med. 2024; 391: 504-514.

CRENESSITYTM (crinecerfont). US Prescribing Information. Neurocrine Biosciences. Dec 2024.

Merke DP, et al. N Engl J Med. 2020;383(13):1248-1261.

Mallappa A, et al. Nat Rev Endocrinol. 2022; 18(6):337-352.

Sarafoglou K, et al. N Engl J Med, 2024; 391 : 493-503.

Speiser PW, et al. J Clin Endocrinol Metab. 2018; 103(11):4043-4088.

April 9, 2025

Theresa Costales MD
CMO, AHCCCS Pharmacy & Therapeutics Committee
801 E. Jefferson Street
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Re: Removing Medicaid Restrictions to Schizophrenia Long-Acting Injectable Treatment

Dear Dr. Costales:

On behalf of the Alliance for Patient Access, I am writing to encourage you address the barriers to access for long-acting injectable antipsychotics at the upcoming P&T Committee meeting. Harmful insurance utilization management tactics, including onerous prior authorizations and unnecessary step therapy requirements, are currently preventing health care providers and their patients from being able to access the full array of treatment options.

Founded in 2006, AfPA is a national network of policy-minded health care providers who advocate for patient-centered care. AfPA supports policies that reinforce shared decision-making, promote personalized care and protect the clinician-patient relationship. Motivated by these principles, AfPA members participate in clinician working groups, advocacy initiatives, stakeholder coalitions and the creation of educational materials. AfPA's Mental Health Working Group convenes clinicians focused on ensuring policy allows for appropriate mental health care access.

Prior authorization is a tactic used by insurance companies to limit insurer costs. Before receiving access to the prescribed treatment, insurers often require the clinician to complete prior authorization paperwork justifying the treatment. This often leads to treatment delays for days or even weeks. For patients with serious mental illness such as schizophrenia, excessive delays can have a devastating impact, leading to exacerbation of symptoms.

Step therapy is a tactic used by many payers that requires patients to try and fail insurer-preferred options, often based on cost, prior to receiving approval for the preferred treatment as dictated by the prescribing clinician. Insurers may require failure on more than one medication, leading to significant delays before getting to a successful therapy. For patients with mental health considerations, "fail first" policies can have a devastating impact. Many older, first-generation antipsychotics have several negative side effects, including but not limited to weight gain, seizures, tardive dyskinesia and sedation.[1]

The Pharmacy & Therapeutics Committee taking action is critically important, as people living with mental health conditions often do not have time to wait for insurance hurdles to be resolved. Studies of state Medicaid programs have found that lack of access to SMI treatment contributes to a higher

[1] https://www.goodtherapy.org/drugs/anti-psychotics.html

rate of negative outcomes, including increased emergency room visits, hospitalizations, homelessness or incarceration. In addition, these negative outcomes are particularly burdensome in communities of color.[2] Improving patient access to these medications has the potential to reduce financial and administrative burdens on the health care system, but other social institutions, as well.

People with untreated SMI run the risk of several serious, negative outcomes. A 2014 study found that homeless individuals with SMI have high non-adherence rates: 47.1 percent for psychiatric medications and 70 percent for schizophrenia medications.[3] Medication access and adherence are key to positive outcomes, including stable housing. Adherence is instrumental in stabilizing those living with SMI, which can prevent homelessness and assist patients transitioning into housing. It is important to recognize the improvements to adherence that long-acting injectables offer to a community that often struggles with continuity of care and has high rates of nonadherence.

We encourage you to ensure the formulary allows for ease of access to appropriate therapies. These modest, but impactful changes would significantly benefit beneficiaries seeking to use long-acting injectables. If you have any questions, please contact Casey McPherson at cmcpherson@allianceforpatientaccess.org.

Sincerely,

Executive Director
Alliance for Patient Access

[2] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793285
[3] https://pubs.lib.umn.edu/index.php/innovations/article/view/342