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Requestor Name: Adrienne Simmons
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Requestor Fax #: ..
Representing Other? Yes
Representative of: National Viral Hepatitis Roundtable
Non-affiliated/private?
Statement of No Conflicts:
Disclosures:Yes
Organization1/Role1: Gilead Sciences / Hepatitis Delta Advisory Board, funds provided to institution
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: A PDF of the below testimony was provided to AHCCCSPharmacyDept@azahcccs.gov. April 29, 2022 Re: Hepatitis C Prior Authorization Criteria Dear AHCCCS Pharmacy & Therapeutics Committee, The National Viral Hepatitis Roundtable (NVHR) appreciates the opportunity to submit comments on the prior authorization criteria for hepatitis C virus (HCV) treatment for Arizona Health Care Cost Containment System (AHCCCS) beneficiaries. NVHR is a coalition of patients, health care providers, community-based organizations, and public health partners fighting for an equitable world free of viral hepatitis. In partnership with Harvard Law School's Center for Health Law and Policy Innovation, NVHR tracks and documents HCV treatment access across the country through our Hepatitis C: State of Medicaid Access project ([stateofhepc.org](http://stateofhepc.org/)). Most recently we issued a progress report examining state-level trends in aligning treatment access through state Medicaid programs with evidence-based treatment guidelines. As of January 2022, Arizona was one of only 13 states whose Medicaid program requires that specialists be consulted to prescribe HCV treatment. We commend the P&T Committee's recent steps toward increasing access to HCV treatment by removing the requirement to abstain from substances for three months. However, we remain concerned that access to treatment is limited by the requirement that prescriptions be written by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician. We encourage the P&T Committee to remove all prescriber restrictions. As with sobriety restrictions, state Medicaid programs have trended towards reconsidering and removing these requirements, recognizing that a broader range of health care providers has sufficient capability of managing HCV treatment and will be necessary to achieve population health goals of viral hepatitis elimination, particularly in areas experiencing shortages in specialists. Fortunately, prescribing HCV treatment for non-cirrhotic and compensated cirrhotic patients has been made easy with the adoption of the American Association for the Study of Liver Disease and the Infectious Disease Society of America (AASLD/IDSA) Simplified Treatment Algorithm. This systematic process walks prescribers step-by-step through evidence-based eligibility criteria, pretreatment assessments, and recommended regimens. The simplicity of the guidelines and pan-genotypic nature of preferred agents makes prior authorizations administratively burdensome and obsolete. A study in Rhode Island found that the complete prior authorization process from prescription to DAA acquisition took 45-120 minutes per patient, longer with a protracted denial and appeals process. Ultimately NVHR encourages Arizona to follow in the footsteps of the 12 state Medicaid programs who have removed prior authorizations for most patients. Arizona has systems in place to safely expand the number of midlevel practitioners and primary care physicians engaged in the treatment of HCV infection, in accordance with AASLD/IDSA guidance. First, the Arizona ECHO program has successfully supported providers who are new to prescribing HCV therapy by offering access to specialists when it is necessary to do so, such as in the infrequent case of decompensated cirrhosis. The removal of this prior authorization requirement would maintain this support system while better utilizing scarce healthcare resources. Of the ten states who offer ECHO training programs, Arizona is one of only three states who requires prescriptions to be written by or in consultation with a specialist. Additionally, pharmacists who are dispensing HCV treatment are trained and pharmacy software are designed to assess clinical appropriateness and drug interactions for all medications. Given the favorable safety profile of HCV treatment, having pharmacists manually review HCV prior authorizations is a costly, redundant, and inefficient process. Ultimately, prior authorizations place an undue administrative burden on prescribers, which takes away time and resources from other life-saving care and increases patients' risk of hepatocellular carcinoma, liver failure, and death. We look forward to the prospect of Arizona making significant progress towards viral hepatitis elimination goals by removing all prescriber restrictions and will monitor developments with great interest. Sincerely, Adrienne Simmons, PharmD, MS, BCPS, AAHIVP Director of Programs, National Viral Hepatitis Roundtable
Drug/Product: Epclusa, Mavyret, sofosbuvir/velpatasvir
Therapeutic Drug Class: Hepatitis C Direct Acting Antiviral Agents
Testimony Oral?
Testimony Written? Yes

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Representing Other? Yes
Representative of: Neuromedicine Center
Non-affiliated/private?
Statement of No Conflicts:Yes
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: I am a neurologist practicing in Arizona for the past 20 years and see more than 20 migraine patients a month and have found that the CGRP antagonists help to reduce the severity of the migraine episodes significantly by more than 50 %. Would strongly recommend approval of the CGRP antagonists for both breakthrough/acute and preventive/prophylactic treatments.
Drug/Product: UBRELVY & NURTEC-Acute Treatment AIMOVIG/QUILIPTA/AJOVY & EMGALITY-Preventive
Therapeutic Drug Class: CGRP Antagonists
Testimony Oral?
Testimony Written? Yes

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Representing Other?
Representative of:
Non-affiliated/private? Yes
Statement of No Conflicts:Yes
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: ASAM National Practice Guideline in outpatient is the utilization of this medication. HOW can AZ Medicaid not readily afford this access?
Drug/Product: Lucemyra
Therapeutic Drug Class: alpha-2 adrenergic agonists
Testimony Oral?
Testimony Written? Yes

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Representing Other?
Representative of:
Non-affiliated/private? Yes
Statement of No Conflicts:Yes
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: I am an addiction specialist doctor that has treated hundreds of patients struggling with their life to stop using opiate prescription drugs, heroin, and fentanyl. Lucemyra has been the most successful drug to help patients through the tremendously difficult period after they have stopped using. The medication significantly helps reduce the nausea, chills, sweating, muscle spasm, bone pain, feelings of "insects" crawling on their skin, anxiety, insomnia, etc that makes stopping their drug so incredibly difficult. Once a patient has stopped using with the benefit of Lucemyra, only then can they use an opiate blocker called Naltrexone that prevents the patients from the euphoric effects of the opiates and also blocks their cravings. Lucemyra is a most valuable and medically necessary medication for these patients. I know that there are many of my patients still alive due to the use of this medication. Lucemyra is the only FDA approved non-opiate drug for the relief of opiate withdrawal. Please approve this life saving medication. I thank you and the families, friends and future patients of mine thank you in advance for approving this med.
Drug/Product: Lucemyra
Therapeutic Drug Class: Non-Opiate treatment for opiate/heroin/fentanyl withdrawal
Testimony Oral?
Testimony Written? Yes

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Representing Other? Yes
Representative of: Arizona Psychiatric Society
Non-affiliated/private? Yes
Statement of No Conflicts:Yes
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: On behalf of over 900 practicing psychiatrists and their patients, the Arizona Psychiatric Society respectfully submits these comments for your consideration. All psychiatric providers in the State of Arizona, along with ACCCHS and the Pharmacy and Therapeutics Committee, have a common goal of wanting to do whatever we can to ensure AHCCCS patients receive exceptional care. We recognize and sincerely appreciate the hard work and dedication to providing mental health care in our community, which continues to require flexibility and perseverance as we face the continued course of the pandemic and possible end of the public health emergency status for the United States overall. We share thanks and gratitude for everyone who continues to do this challenging work, as we believe the impacts of the pandemic will resonate throughout behavioral health well beyond the end of the public health emergency status. As we have consistently provided written testimony regarding, one of our main concerns for our patients and AHCCCS members continues to be the placement of limitations on prescribing practices and medications that could potentially result in poor or substandard care. We believe in providing the best care for our patients. We also understand that resources are not limitless, and that, we need to work with you and AHCCCS to provide care in a financially responsible way. It is from this perspective that we encourage a continued open access to psychotropic agents that have demonstrated clinical value. These include anti-depressants (other and SSRIs), long-acting atypical antipsychotics (LAIs), oral atypical second-generation antipsychotics, stimulants and related agents, and opiate dependence treatments such as MAT (medication assisted treatments). We would like to encourage the AHCCCS Pharmacy and Therapeutics Committee, in reviewing medications for consumers, to consider the following evidence regarding Medicaid formulary restrictions for those with chronic and serious mental illness. Restricted access to atypical antipsychotics has been shown to be associated with decreased medication adherence, increased treatment discontinuation, and increased healthcare costs. In several comprehensive, multi-state retrospective studies of Medicaid formulary restriction(1, 2, 3), the following effects were seen: . Patients with schizophrenia were more likely to require hospitalization, had 23% higher inpatient costs and 16% higher total costs. . Patients with schizophrenia had worsened adherence to treatment, with 12-29% rates of medication discontinuation. . Patients with bipolar disorder had 20% higher inpatient costs and 10% higher total costs. . Patients with schizophrenia were 22% more likely to be incarcerated. Arizona Psychiatric Society May 3, 2022, Page Two . Patients were more likely to be re-prescribed medications which had been ineffective in the past. . A consistent finding has been that formulary restrictions for psychotropic medications used to treat conditions like these do not significantly lower Medicaid total expenditures for this population. Other research has suggested that treatment delays due to the prior authorization process can significantly contribute to patient relapse and decompensation as risk for rehospitalization in patients with schizophrenia increases by 50% in the first ten days following a missed prescription refill (4). It has been demonstrated that compared with use of oral antipsychotics, use of LAIs was associated with significantly fewer readmissions of Medicaid patients with schizophrenia within 60 days after an index hospitalization (5). Studies looking at the direct cost analysis has shown that Medicaid-insured patients with schizophrenia initiating treatment with LAIs, the mean number of all-cause hospitalizations and hospitalization days were reduced by 24% and 31% (p<0.0001) compared with baseline. Results from large cohort studies provide naturalistic real-world evidence of the utility of LAIs in patients with schizophrenia and suggest that these agents help to reduce the risk of relapse across all age groups (7). The primary results of a meta-analysis suggest that LAIs are associated with a 20% higher reduction in hospitalization rates for schizophrenia patients compared to oral antipsychotics. (6) Additionally, typical, or "first generation" antipsychotics have a significantly higher association with a disfiguring and irreversible side effect like tardive dyskinesia. Studies which have purported to demonstrate no clear advantage for atypical over typical antipsychotics have generally not factored in the difference in incidence rates of tardive dyskinesia, which have been consistently found to be at least and, in some cases, much greater than 5%/year for patients prescribed typical antipsychotics versus less than 1%/year for patients taking atypical antipsychotics. Patients with chronic and serious mental illness can be psychiatrically, medically, and socially complex. They are among the most vulnerable of the populations served by AHCCCS. Maintaining their psychiatric and medical stability in the community requires clinicians adhere to best practices for treatment of these conditions. Having access to the entire spectrum of needed medications is especially important for them. In order to provide effective treatment for patients with chronic and serious mental illness, it is essential that clinicians be able to choose among a variety of agents with different profiles and characteristics. Individual variations in medication response and ability to tolerate medication side effects can be substantial and are critical considerations in determining whether an individual will consistently adhere to treatment and remain stable in the community or experience a cycle of repeated hospitalizations and emergency room visits. Similar information and comments can be provided about the other drug classes mentioned above. On behalf of the Arizona Psychiatric Society, we thank the Committee for your consideration of our recommendations as we work together on this important issue. Please reach out if there are any other ways we could provide additional input, help, and support.
Drug/Product: All products within the classes relating to psychiatric care, including but not limited to: . Opiate Dependence Treatments . Antipsychotics - Oral Atypicals 2nd Generation . Antipsychotics - Atypical Long-Acting Injectables . Stimulants and Related Agents
Therapeutic Drug Class: . Opiate Dependence Treatments . Antipsychotics - Oral Atypicals 2nd Generation . Antipsychotics - Atypical Long-Acting Injectables . Stimulants and Related Agents
Testimony Oral?
Testimony Written? Yes

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Representing Other? Yes
Representative of: Arizona Peer and Family Coalition
Non-affiliated/private?
Statement of No Conflicts:Yes
Disclosures:Yes
Organization1/Role1: Arizona Peer and Family Coalition / Advocacy Co-Chair
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: On behalf of the Arizona Peer and Family Coalition, we are in full support of all individuals with mental health issues obtaining access to the most appropriate medication at the right time. Access to a full range of medications is an extremely important component of recovery. The necessary psychotropic medications, and their combination with other services and supports, are an essential component of one's health and well-being. For some it may be a matter of life or death. Most often, the combination of psychotropic medications and other services keep individuals living within their community, continued employment, working their recovery and living a healthy and productive life.
Drug/Product: Long-acting injectable anti-psychotics
Therapeutic Drug Class: Na
Testimony Oral?
Testimony Written? Yes

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Representing Other? Yes
Representative of: AbbVie
Non-affiliated/private?
Statement of No Conflicts:
Disclosures:Yes
Organization1/Role1: AbbVie / Employee
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: See attached written testimony:Medicaid Written Testimony for QuliptaŽ (atogepant) for adult patients with Episodic Migraine . Qulipta, an oral calcitonin gene-related peptide (CGRP) receptor antagonist, was approved on September 28, 2021, for the preventive treatment of episodic migraine in adults. It is the only approved CGRP product that has three doses. The recommended dose is 10mg, 30mg, or 60mg depending on dosage modifications for drug interactions and special populations, as listed in the prescribing information.1 . Migraine is a complex chronic disease that has significant patient and economic burden. A migraine patient with frequent headache days may experience significant loss in work productivity and have higher total all-cause direct and indirect costs compared to a non-migraine patient and therefore may require a preventive medication such as atogepant.2 . Results from the ADVANCE clinical trial were recently published in the New England Journal of Medicine3 and serve as part of the basis for FDA approval of Qulipta in adult patients with episodic migraine. . ADVANCE was a Phase 3, multicenter, randomized, double-blind, placebo controlled, parallel-group study that evaluated once daily atogepant 10mg, 30mg, or 60mg versus placebo for 12 weeks.3 A total of 910 participants were enrolled, and 873 were included in the efficacy analysis. The primary endpoint of "change from baseline in mean monthly migraine days (MMD) across 12 weeks compared to placebo" was met by all three doses. o The changes from baseline across 12 weeks were −3.7 days with 10mg atogepant, −3.9 days with 30mg atogepant, −4.2 days with 60mg atogepant, and −2.5 days with placebo. The mean differences from placebo in the change from baseline were −1.2 days with 10mg atogepant (95% CI, −1.8 to −0.6), −1.4 days with 30mg atogepant (95% CI, −1.9 to −0.8), and −1.7 days with 60-mg atogepant (95% CI, −2.3 to −1.2); P<0.001 for all comparisons with placebo.3 o The benefits of atogepant were evident as early as the first full day after administration; 873 subjects (mITT population) from the ADVANCE trial were evaluated for the time course of efficacy of atogepant for the preventive treatment of episodic migraine. Percentages of participants reporting a migraine on post-dose Day 1 ranged from 10.8% - 14.1% for atogepant versus 25.2% with placebo (p ≤ 0.0071).4 o All 6 key secondary endpoints compared to placebo were met for the 30 mg and 60 mg doses, including 3 patient reported outcomes.3 These doses significantly improved function as it relates to social and work-related activities. All three doses of atogepant significantly reduced mean monthly headache days, and mean monthly acute medication use days by approximately 50%; 55-60% of patients experienced at least a 50% reduction of migraine days across the 12-week treatment period. o During weeks 9-12, 61-71% of patients experienced a 50% reduction of migraine days, approximately 43-50% experienced a 75% reduction, and approximately 21-28% of patients experienced a 100% reduction of migraine days.3 . There are no contraindications, warnings, or precautions for Qulipta in the Prescribing Information.1 The most common adverse events (incidence at least 4% and greater than placebo) reported in the 12-week, placebo-controlled trials were nausea, constipation, and fatigue. Discontinuation rates due to adverse reactions for nausea, constipation and fatigue/somnolence were 0.5%, respectively. No Hy's Law cases were identified. . Given the findings of the ADVANCE study, we ask that you consider making Qulipta available as Preferred on the AHCCCS Arizona Medicaid PDL for prevention of migraine in adult patients with Episodic Migraine. References: 1. QULIPTA package insert, Chicago, IL: AbbVie, Inc.;2021. [www.RxAbbvie.com](http://www.rxabbvie.com/) 2. Buse DC, et al. J Manag Care Spec Pharm. 2020; ;1-10. doi:10.18553/jmcp.2020.20100 3. Ailani J, et al. N Engl J Med. 2021;385:695-706. 4. Schwedt TJ, et al. Cephalalgia. 2022;42(1):3-11.
Drug/Product: Qulipta(R) (atogepant)
Therapeutic Drug Class: Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist
Testimony Oral?
Testimony Written? Yes

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Representing Other? Yes
Representative of: Arizona Liver Health
Non-affiliated/private?
Statement of No Conflicts:Yes
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: Arizona needs to join a growing number of states and remove the remaining restrictions to access for patients to receive Hepatitis C treatment. Those restrictions are (1) consultation with a specialist and (2) prior authorization. Without these barriers removed, we will continue to struggle to elimination Hepatitis C among the citizens of our state.
Drug/Product: Hepatitis C DAA's (direct acting antiviral therapies)
Therapeutic Drug Class: Antiviral Therapies for Hepatitis C infection
Testimony Oral? Yes
Testimony Written? Yes

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Representing Other?
Representative of:
Non-affiliated/private? Yes
Statement of No Conflicts:Yes
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: I highly recommend that Trulicity medication continue to be on AHCCCS plan formularies for the state of Arizona. Diabetic patients benefit, and the state benefits by reducing diabetes complication ER visits with improved glycemic control.
Drug/Product: Trulicity by Lilly
Therapeutic Drug Class: GLP-1 anti-diabetic
Testimony Oral?
Testimony Written? Yes

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Representing Other?
Representative of:
Non-affiliated/private? Yes
Statement of No Conflicts:Yes
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: As a PCP, I have seen the outcomes of Trulicity on my patients. Pt's tend to lose weight and have a increased reduction of their A1C. Pt's also tend to be very compliant with Trulicity as this is once a week and easy for them to use. I have seen more compliance and A1C reduction with this medication than any other GLP-1 currently on the market. I have most of my patients on this and it would be hard to maintain compliance if this is removed from the formulary
Drug/Product: Trulicity
Therapeutic Drug Class: GLP-1
Testimony Oral?
Testimony Written? Yes

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Representative of:
Non-affiliated/private?
Statement of No Conflicts:
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: I would like to continue to be able to use long acting injectible options for treatment as LAI treatment prevents decompensation, noncompliance.
Drug/Product: Aristada LAI Abilify Maintena LAI Invega Sustenna LAI Invega Trinza LAI
Therapeutic Drug Class: Second Generation Antipsychotic medications
Testimony Oral?
Testimony Written? Yes

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| PSWebteam@magellanhealth.com |

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Requestor Name: Stacy Underwood, DNP
Requestor Company: Southwest Behavioral Health Recovery Transition Program
Requestor Address1: 2042 N 35th Ave.
Requestor Address2:
Requestor City: Phoenix
Requestor State: AZ
Requestor ZipCode: 85009-
Requestor Preferred Email Address: stacyun@sbhservices.org
Requestor Telephone #: 602.272.5650
Requestor Fax #: 602.272.2336
Representing Other?
Representative of: Southwest Behavioral Health
Non-affiliated/private?
Statement of No Conflicts:
Disclosures:Yes
Organization1/Role1: Alkermes / Speaker Bureau
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: Importance for the continued availability of Long Acting Injections for the treatment of Schizophrenia. Although all LAI's are used in my practice, this testimony is specific for Aristada.
Drug/Product: Aristada; Aristada Inition
Therapeutic Drug Class: Antipsychotic
Testimony Oral?
Testimony Written? Yes

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| to AHCCCSPharmacyDept, SMartinez, Tlkounshttps://mail.google.com/mail/u/1/images/cleardot.gif |

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Requestor Name: Tracy Kouns
Requestor Company: Redemption Paychiatry
Requestor Address1: 12424 N 32nd St
Requestor Address2:
Requestor City: Phoenix
Requestor State: AZ
Requestor ZipCode: 85032-
Requestor Preferred Email Address: Tlkouns@gmail.com
Requestor Telephone #: 615.294.3377
Requestor Fax #: ..
Representing Other?
Representative of:
Non-affiliated/private?
Statement of No Conflicts:Yes
Disclosures:
Organization1/Role1: /
Organization2/Role2: /
Organization3/Role3: /
Organization4/Role4: /
Summary of Testimony: Rexulti has been a wonderful augmentation agent for my patients struggling with severe depression. It's especially helpful for patients who are dealing with comorbid anxiety or PTSD. There are few side effects and the medication is better tolerated than other atypicals.
Drug/Product: Rexulti
Therapeutic Drug Class: Atypical antipsychotic
Testimony Oral?
Testimony Written? Yes