A recent study finds that dosage/duration limitations, prior authorization, prescription limitations, lack of coverage, and utilization management policies limit accessibility to medication for the treatment of opioid use disorder.

Use of illegal opioids such as heroin and the non-medical use of certain prescription opioid pain medications, such as oxycodone, have risen to epidemic levels, with rates continuing to soar. Deaths from opioid overdose have tripled since 1990 and are now comparable to deaths resulting from motor vehicle accidents in persons under age 65 (Centers for Disease Control, 2011).

Additionally, in 2010, DAWN estimated that approximately 2.3 million emergency room visits resulted from drug misuse or abuse; 51 percent involved nonmedical use of pharmaceuticals.

FDA approved medications for the treatment of opioid use disorder, including methadone, buprenorphine and naltrexone are effective, safe and cost-effective yet continue to be underutilized and inaccessible under both Medicaid and private insurance.

What are the barriers to these life saving medications?

In both the public and private insurance markets payers have enacted time consuming and often dangerous utilization management barriers with little to no medical basis.

Policies such as “fail first” (also referred to as “step therapy,”) complex prior authorization requirements and dosage limitations serve to prevent patients from full access to methadone, buprenorphine and naltrexone. Further, provider prescribing restrictions including limits on numbers of patients and prior authorization further prevent these lifesaving medications from full utilization.

Dosage/Duration Limitations: Both public and private insurance providers frequently employ dosage and/or duration limitations when covering medications for the treatment of opioid use disorder that may not correspond to clinically recommended dosages of the medication. Further, in some cases, public insurance has placed lifetime limitations on these medications – unlike other lifesaving medications, with one northeast state establishing a 24 month lifetime limit for methadone.
Additionally, 11 states have implemented lifetime limits on prescriptions for buprenorphine, and a total of 14 states have established a maximum daily dose of buprenorphine after six months or more of therapy, ranging from 8 to 16 mg. These dosage limitations seem to have no medical basis and do not correspond to established clinical guidelines for the safe usage of buprenorphine. Further, sharp dosage limitations for buprenorphine may result in serious medical effects including miscarriages among pregnant women. Because dose limitations are frequently below the FDA-approved range, it is unclear whether they are safe and effective.

**Prior Authorization:** Prior authorization requires that a patient meet various criteria (as verified by their prescriber) in order for prescriptions to be approved. Such criteria vary between states and private insurers and can range from requirements for counseling to “active participation in a comprehensive rehabilitation program that includes psychosocial support.” While counseling and/or psychosocial intervention combined with medication has been found to be extremely beneficial to those suffering from opioid use disorders, insurers have increasingly required such services while failing to provide coverage for such treatments concurrently with use of medications. The health plans’ policies for coverage are not often easily available to the prescriber or patient. Additionally, once approved prior authorizations often are subject to time limitations on the use of the medication, such as 3 months. Unlike medications for other chronic conditions, prior authorization requirements are common among medications for the treatment of opioid use disorder and often require days or weeks for approval, while patients remain at-risk for relapse, overdose or death. Further, benefit classification.

**Prescribing Limitations:** In addition to barriers that prevent patient access to both information and medications, practitioners are also burdened with additional federal prescribing restrictions that are only applied to medications for the treatment of opioid use disorder. Under DATA 2000, physicians must be trained to become qualified; only qualified physicians are permitted to prescribe buprenorphine for the treatment of opioid use disorder once they meet certain criteria. Once that criterion is met, however, prescribers are limited to treating only 100 patients (Drug Addiction Treatment Act of 2000). In a recent survey, 43% of DATA-waived ASAM members reported the 100-patient prescribing limit as a barrier to treatment.

**Lack of Coverage:** Methadone may be provided for the treatment of opioid dependence only through a licensed specialty treatment program. Many public and private health plans exclude coverage for this life-saving treatment, neglecting to offer a needed level of care for treating opioid use disorder. Further, benefit classification can present significant barriers as well. Naltrexone, for example, is often covered as a medical benefit rather than a prescription benefit, which results in significant coverage issues for both patients and providers.

**Fail First:** “Fail First,” also referred to as “Step Therapy,” requires that a patient attempt (and presumably fail) less costly therapies prior to receiving coverage for a targeted medication. While matching patients with appropriate medications is extremely important, written utilization management and/or drug utilization review committee notes often show primarily financial, rather than quality management or patient life-saving concerns as justification for use of Fail First policies.

### POLICY IMPLICATIONS

As the Affordable Care Act rolls out in 2014, millions of previously uncovered patients will have access to coverage for substance abuse treatment. As such, both public and private insurers will see an increase in demand for evidence-based and cost-saving treatment for opioid use disorder. Further, health plans will be called upon to make coverage and utilization management requirements and approval processes more consistent, equitable and comprehensible to the average patient and provider. Arbitrary restrictions that serve as barriers to provider and patient access to medication for the treatment of opioid use disorder must be lifted in order to safely, efficiently and properly combat the ever increasing opioid epidemic.