REVIEW

# Common Elements in Opioid Use Disorder Guidelines for Buprenorphine Prescribing

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## ABSTRACT

**OBJECTIVES:** This study sought to formulate a consolidation of guidelines representing best practices related to office-based opioid treatment (OBOT) of opioid use disorder (OUD) using buprenorphine. It also demonstrates how a set of evidence-based guidelines may be linked with claims data to leverage analytic techniques that drive cost-effective, positive health outcomes.

**STUDY DESIGN:** Literature review of US and international guidelines for OBOT using buprenorphine for OUD.

**METHODS:** The study conducted a review of currently available US and several international guidelines from 2009 to 2018 published on OUD and the use of buprenorphine in OBOT. Guidelines were consolidated based on common elements. The process of correlating common elements with available commercial and state Medicaid claims data is described, including which elements are amenable to analysis along with relative complexity.

**RESULTS:** Seven guidelines met inclusion criteria and are presented as 3 tables, organized by clinical themes and phase of care related to OBOT use of buprenorphine for OUD. Themes included establishing care, monitoring treatment stability and engagement, and nonpharmacologic treatment to improve outcomes. Areas of agreement and divergence between guidelines are highlighted. Specific components are identified as they relate to metrics of interest to public and private payers.

**CONCLUSIONS:** Among US and international guidelines for treatment of OUD, common themes are readily identified and may indicate agreement in regard to interventions. Linking pharmacy and medical billing claims data to evidence-supported best practices provides public and private payers the ability to track individual patients, facilitate high-quality care, and monitor outcomes.


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Despite widespread efforts by private- and public-sector healthcare providers, organizations, and policy makers, the opioid epidemic in the United States has shown few signs of abating. Widespread opioid prescribing has resulted in many patients developing opioid use disorder (OUD), which is described by the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, as "a problematic pattern of opioid use leading to clinically significant impairment or distress" with at least 2 specific criteria within a 12-month period.[1] Based on cross-sectional data from between 2006 and 2011 from the National Survey on Drug Use and Health (NSDUH), the number of individuals in the United States with OUD was estimated to be 2.1 million.[2] Furthermore, 2016 NSDUH results showed that approximately 3.3 million Americans engaged in nonmedical use of prescription opioids within the past month, suggesting that the number of additional individuals at risk for developing OUD is substantial.[3]



The CDC reported 2016 data showing 42,249 opioid-related drug overdose deaths, driven primarily by an increase in deaths involving heroin and synthetic opioids believed to be fentanyl derivatives.[4] This marks a continuing trend of a rising death toll from opioid-related deaths over the preceding decade, with growing focus on illicit drug use and less on opioid prescribing alone.[5] Even with the ongoing emphasis on healthcare provider education, increased regulations limiting prescription opioids, and expansion of prescribing limits for buprenorphine, OUD remains undertreated and prevalence continues to climb, secondary to illicit opioid use.

OUD and opioid-related adverse events including overdose are associated with significant societal costs, morbidity, and mortality. The economic burden of opioid overdose, abuse, and dependence includes medical and OUD treatment costs, lost work productivity, and the societal costs of those who enter the criminal justice system. Using 2013 data, this total economic burden was estimated at $78.5 billion annually, with $28.9 billion associated with healthcare and substance abuse treatment costs.[6] However, a 2017 report by the US Council of Economic Advisors states that previous figures underestimated the total healthcare burden of OUD by not including the economic costs of overdose deaths and

illicit use, and their analysis reflects a cost of $504 billion in 2015.[7] Results of analyses using commercial insurance databases have shown that opioid abuse results in excess healthcare costs per patient of between $10,627 and $14,810 annually.[8,9] A 2015 review of the available literature using data from 2009 to 2014 regarding increased healthcare costs for opioid users suggested that the average cost to a payer for a patient with OUD is $23,000 to $25,000 per year, of which increased costs attributable to OUD are approximately $15,000 per patient annually.[10]

**TAKEAWAY POINTS**

- Opioid use disorder (OUD) continues to be a widespread and expensive health problem, with illicit use currently driving increased adverse events and costs disproportionately directed to public and private managed care organizations and health plans.
- We propose a consensus of elements common to US and several international guidelines as the basis for an analytic approach to identifying patients in need of targeted intervention and providers demonstrating exemplary clinical practice.
- An analytic approach to using data already available to public and private health plans and managed care organizations has the potential to effectively target interventions and resources to the time and place they are needed in order to make a cost-effective, high-value impact on the care of individuals with OUD.

OUD is fundamentally a public health problem, and its high economic burden makes it a source of financial incentive for both commercial and public (ie, Medicare or state Medicaid) health plans and accountable care organizations—all hereafter referred to as payers—to facilitate adequate treatment of patients with OUD. In early 2017, the chief executive officers of several prominent payer organizations approached this study's sponsor specifically requesting assistance to monitor OUD treatment and identify providers of high-quality care using claims data. The comprehensive review presented herein represents the initial analysis critical to the creation of a surveillance solution for OUD using data analytics. High-quality care guidance must begin with a consolidation of available evidence to identify and implement best practices, yet multiple national and international stakeholder organizations publish OUD treatment guidelines. Practice pattern variation is inevitable when each organization promotes the recommendations of its own subject matter experts. Nevertheless, harmonious definitions can be leveraged to identify and track individuals with OUD to provide them with appropriate treatment resources, prioritize early intervention, and promote sustained recovery. Effectively achieving this aim requires completing several crucial tasks: (1) tracking members who are at risk for OUD or currently diagnosed with OUD, (2) coordinating care and facilitating access to high-quality providers, and (3) measuring treatment outcomes for these patients as well as determining the impact of providers.

### Proposed Solutions

Our proposed solution for these problems employs a summary of widely recognized treatment guidelines and clinically validated best practices. We present a review of the major US, and several international, OUD treatment guidelines where consensus among common elements leads to best practice and areas of discrepancy may account for practice pattern variation. By culling the shared elements across a number of guidelines, we are able to focus on aspects that are measurable and actionable for a payer that desires an evidence-based, consistent approach to managing OUD. Tracking actionable aspects of the consolidated common elements among these guidelines requires linking them to relevant medical billing and pharmacy claims data. This framework provides a foundation for defining the criteria by which at-risk patients are identified and the quality of treatment outcomes is assessed. Payers can utilize this data management and solutions approach to identify high-value providers and subsequently create a network of higher-quality and accessible recovery centers to which patients with OUD may be directed; this would thus drive high-quality outcomes and lower healthcare costs among individuals with OUD.

## METHODS

PubMed, Embase, and Google Scholar were searched using the terms *opioid use disorder*, *medication assisted treatment*, *opioid addiction*, *opioid dependence*, and *buprenorphine prescribing*, filtering search results for *systematic reviews* and *guidelines*. Fifteen guidelines were initially identified, including 10 from the United States and 5 international. US guidelines were included if they specifically addressed office-based opioid treatment (OBOT) with buprenorphine and were excluded if they were written for individual states or regions, health conditions, or age groups. International guidelines were included if medications and treatment paradigms resembled practice in the United States. For example, international guidelines were excluded if they promoted pharmaceutically prepared heroin as a treatment option or if prescribing and dispensing of medication-assisted treatment (MAT) did not require a medical license. Guidelines were independently reviewed by the authors and categorized according to common themes modeled after the CDC's "Common Elements in Guidelines for Prescribing Opioids for Chronic Pain."[11] An initial list of common elements for MAT and OBOT was created, with topics commonly proposed by the individual guidelines retained and those that seemed to be contextually unique to a particular guideline omitted. The collection of common elements was individually verified through searches of available state Medicaid and commercial medical and pharmacy claims data provided by axialHealthcare, Inc. Simple measurement strategies were sufficient for many of the common elements because they were readily identifiable in claims data. However, others required creation of definitions and application of specialized analytics.

**TABLE 1.** Establishing Care in OUD

| Common Elements in MAT Guidelines for Buprenorphine Use in OUD | | | | |
|---|---|---|---|---|
| | US OBOT | | | |
| Provider Action | ASAM[12] | SAMHSA[13,14] | VA/DoD[15] | FSMB[16] |
| Medical history and physical assessment | • Comprehensive medical history<br>• Physical exam<br>• Evaluate for infectious diseases<br>• Pregnancy<br>• Lab tests | • Conduct focused physical exam<br>• Complete history<br>• Assess symptoms of intoxication or withdrawal<br>• Lab tests: UDT, Etoh, HIV, pregnancy, hepatitis B or C, LFTs | History and physical exam, lab tests | • Physical exam<br>• Thorough medical history<br>• Communicable diseases<br>• UDT, PDMP |
| Mental health assessment | • Psychiatric stability<br>• Psychiatric disorders | • Mental status examination<br>• Formal psychiatric assessment (if indicated) | • Mental status examination<br>• Psychiatric stability<br>• Psychiatric disorders | • Psychiatric history<br>• Psychiatric disorders<br>• Readiness to participate in Tx |
| Substance use history | • Confirm OUD diagnosis<br>• Substance abuse history | • Confirm OUD diagnosis<br>• Screen for other SUDs including Etoh, BZDs<br>• Assess recent abuse | • Confirm OUD diagnosis<br>• Offer Tx for each SUD | • Confirm OUD diagnosis, use of other substances<br>• Past Tx experience |
| Social history | • Identify barriers to recovery<br>• Living situation<br>• Financial concerns<br>• Social support | • Social support<br>• Family history<br>• Readiness to change | Assess psychosocial functioning and environment | Determine status:<br>• Social supports<br>• Family/friends<br>• Housing<br>• Employment<br>• Finances<br>• Legal problems |
| Psychosocial assessment | • Assessment of psychosocial needs<br>• Medications but one aspect of Tx | • Needs assessment<br>• Incorporate plan for engaging in psychosocial interventions into Tx plan | • Needs assessment<br>• Supportive counseling<br>• Referral to community services | Baseline assessment; level of psychological and social functioning or impairment |
| Patient selection | • OBOT vs OTP, consider:<br>› Psychosocial situation<br>› Co-occurring disorders<br>› Tx retention vs risk of diversion<br>• Active use of other drugs associated with poorer prognosis<br>• Not a reason to deny Tx | OBOT vs OTP:<br>• Patient preference<br>• Social circumstances<br>• Addiction severity<br>• Motivation and desire for Tx<br>• Psychiatric needs<br>• Affordability of treatment | • OBOT vs OTP:<br>› Patient preference<br>› Stable patients<br>› Provide needed resources<br>› None/few failed attempts at Tx<br>• Difficulty accessing OTP | OBOT:<br>• Ability to offer/refer for psychosocial services<br>• Readiness to change<br>• May be candidates even with previous failures |
| Agreement | Informed consent | • Diversion control plan<br>• Tx agreement<br>• Provider and patient sign | Not specified | Signed Tx agreement or informed consent |

ASAM indicates American Society of Addiction Medicine; BZD, benzodiazepine; Etoh, ethanol/alcohol; FSMB, Federation of State Medical Boards; LFT, liver function test; MAT, medication-assisted treatment; OBOT, office-based opioid treatment; OTP, outpatient treatment program; OUD, opioid use disorder; PDMP, prescription drug monitoring program; SAMHSA, Substance Abuse and Mental Health Services Administration; SUD, substance use disorder; Tx, treatment; UDT, urine drug testing; VA/DoD, Veterans Affairs/Department of Defense; WHO, World Health Organization.

# RESULTS

Seven guidelines met inclusion criteria and were included in the summary of common elements. The 4 from the United States were those of the American Society of Addiction Medicine (ASAM),[12] Substance Abuse and Mental Health Services Administration,[13,14] Veterans Affairs/Department of Defense,[15] and Federation of State Medical Boards.[16] Three additional guidelines met inclusion criteria and represented the international community, including those of the World Health Organization,[17] the British Columbia Centre on Substance Abuse,[18] and the Australian Alcohol and Drug Information Services.[19] The common elements are presented here as 3 separate tables and organized by themes that emerged from the MAT guidelines.

Table 1[12-19] compares recommendations when patients establish care with an MAT provider in an OBOT setting. Guidelines are consistent in recommending a comprehensive medical history, physical examination, mental health assessment, and independent confirmation of OUD diagnosis. A social history and a psychosocial

| Common Elements in MAT Guidelines for Buprenorphine Use in OUD | | | |
|---|---|---|---|
| | International Outpatient Treatment | | |
| Provider Action | WHO[17] | British Columbia[18] | Australia[19] |
| Medical history and physical assessment | • Detailed individual assessment<br>• Physical exam<br>• Medical history<br>• Infectious diseases<br>• Lab tests | • Complete medical history<br>• Physical examination<br>• Infection history (HIV, hepatitis)<br>• Withdrawal assessment<br>• Lab tests | • Physical examination<br>• Medical history<br>• UDT<br>• Test for communicable diseases after stabilization |
| Mental health assessment | Psychiatric history | • Mental health status:<br>› Suicidal ideation<br>• Psychiatric history | • Mental status examination<br>• Assess for intoxication or withdrawal<br>• Psychiatric behaviors<br>• High-risk behaviors |
| Substance use history | • Confirm OUD diagnosis<br>• Harmful use or dependence?<br>• Past Tx experience | • Confirm OUD diagnosis<br>• Chronological substance abuse history<br>• Polydrug use | • Confirm OUD diagnosis<br>• Previous abuse, Tx, and factors leading to relapse |
| Social history | • Living conditions<br>• Legal issues<br>• Occupational<br>• Social<br>• Cultural factors | • Living situation<br>• Supports (family, clergy, friends)<br>• Children at risk<br>• High-risk behaviors | Social problems (unemployment, housing, financial, relationships) |
| Psychosocial assessment | Needs assessment:<br>• Psychotherapy<br>• Social services | • Biopsychosocial assessment<br>• Stressors:<br>› Legal<br>› Employment<br>› Financial<br>› Housing | • Comprehensive biopsychosocial assessment<br>• Case formulation and Tx planning<br>• Influences Tx setting, plan, and need for specialist referral |
| Patient selection | • The degree of supervision of buprenorphine should reflect a balance between Tx acceptability and risk of diversion.<br>• Staff can select patients at lower risk of diversion to receive a lower level of supervision. | • Biopsychosocial stable patients with appropriate UDT may be considered for "carry" or take-home doses.<br>• Carry criteria:<br>› Clinical stability<br>› Patient self-report<br>› Providers and social supports<br>› Physical exam and interview<br>› UDT results<br>• PDMP review for adherence | • Takeaway dosing needs to strike a balance between risk management and patient autonomy.<br>• Takeaway dosing:<br>› Improves patient reintegration<br>› Reduces cost of Tx<br>› Enhances Tx outcomes<br>› Improves patient autonomy<br>› Reduces stigma of Tx |
| Agreement | Patients must give informed consent to Tx | Documented Tx goals and plan; sign Tx agreement | Informed consent in writing and signed |

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needs assessment are also consistently recommended. Tracking these recommended assessments is not possible in claims data alone without access to the electronic health record. A unique feature in US guidelines is patient selection for OBOT versus an opioid treatment program (OTP), for which an assessment of appropriateness is recommended. OBOT is generally recommended for more stable patients who are motivated and more adherent to treatment. Severe psychiatric disorders, polydrug use, and multiple failed treatment attempts may indicate that a patient is more appropriate for an environment with increased supervision and observed dosing (ie, OTP). Although international guidelines do not reflect the structure of OBOT, they assert that more stable patients may be candidates for "carry" or take-home doses similar to OTPs, which generally require daily observed administration of medications. As the risk and complexity of treatment increase, patient placement is critical, and detailed resources like ASAM's criteria exist to provide additional guidance.[12] Examination of the common elements in Table 1[12-19] reveals that only a few binary

**TABLE 2.** Patient Follow-up and Monitoring in OUD

| Common Elements in MAT Guidelines for Buprenorphine Use in OUD | | | | |
|---|---|---|---|---|
| | US OBOT | | | |
| Provider Action | ASAM[12] | SAMHSA[13,14] | VA/DoD[15] | FSMB[16] |
| Visit frequency | • Frequently during initiation (at least weekly)<br>• Stable patients (at least monthly) | • Frequently during induction<br>• Follow-up weekly, biweekly, or monthly depending on stability | Twice weekly, then weekly, then biweekly up to 12 weeks | • Frequently until stable<br>• Follow-up frequency based on compliance and high-risk behaviors |
| Duration | • No time limit<br>• Taper/discontinuation is a slow process and requires careful consideration of factors, including:<br>› Tx engagement<br>› Patient stability<br>› Patient preference<br>› Improved social support | • Tx should last as long as patients:<br>› Benefit<br>› Prefer Tx<br>• Longer Tx associated with positive Tx outcomes<br>• Lifetime Tx acceptable | • No time limit<br>• Longer durations (>90 days) associated with improved outcomes | • Recommend at least 1 year<br>• Longer duration associated with better outcomes<br>• Relapse risk is highest in first 6-12 months of abstinence |
| Prescription frequency | Weekly or monthly | Weekly or monthly | Not specified | • As needed until next visit<br>• Coincides with follow-up based on compliance and high-risk behaviors |
| Usual dosing | • 8-16 mg daily<br>• FDA limits at 24 mg daily<br>• No evidence at higher doses but increased diversion risk<br>• Divide dose for comorbid pain diagnosis | • Nearly all patients will stabilize on daily doses of 4-24 mg<br>• Limited data on higher than 24 mg daily<br>• >24 mg: higher risk of diversion, carefully document justification | • 12-16 mg daily<br>• Moderate evidence higher dosing is more effective<br>• Divide daily dose for concurrent chronic pain | 8-24 mg; some may require up to 32 mg daily |
| UDT | • Baseline<br>• Frequently<br>• Random preferred | • Baseline<br>• Random when stable<br>• Test for metabolites: norbuprenorphine or buprenorphine glucuronide | • Baseline<br>• Frequent<br>• At provider discretion | • Baseline<br>• Routinely<br>• Recommended and included in Tx agreement |
| Pill counts | Unscheduled recall visits | • Recommended<br>• Example provided | Not specified | Recommended and included in Tx agreement |
| PDMP | Verify absence of opioid prescriptions | • Baseline<br>• Periodically check to verify absence of opioid and BZD prescriptions | Not specified | • Baseline<br>• Routinely<br>• Recommended to verify absence of opioid prescriptions |

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outcomes (eg, new patient visits, prescriptions, or laboratory tests for OUD) can be tracked through claims data, and these are generally available with a single *International Classification of Diseases, Tenth Revision*, code or procedure code.

Criteria associated with treatment follow-up and monitoring are found in **Table 2**.[12-19] There is consistency in recommended frequency of follow-up for office visits and prescription renewals: Patients are seen frequently at first and then less often over time as adherence to MAT is demonstrated. Frequency of visits may require periodic adjustment in response to changes in patient stability. Significant disagreement exists between guidelines regarding appropriate dosing of buprenorphine. As multiple buprenorphine formulations are now available with varying potency and amounts of naloxone, it should be noted that references to specific doses in the guidelines use buprenorphine-naloxone (Suboxone) as the reference standard. Guidelines agree that most patients achieve stable maintenance doses between 8 mg and 16 mg daily; however, the appropriateness of daily doses higher than 24 mg is more controversial. Some guidelines cite a lack of evidence for improved efficacy and increased risk of diversion at doses greater than 24 mg daily, whereas others indicate that some patients may require up to 32 mg daily.

Monitoring recommendations vary considerably between guidelines, with several specifically recommending verifying abstinence with the state prescription drug monitoring program (PDMP) and utilizing pill counts, but the majority of available guidelines do not provide specific recommendations in this area. Pill counts and verification PDMP queries are not available in claims data. (Please see **eAppendix** [available at **ajmc.com**] for additional details.)

| Common Elements in MAT Guidelines for Buprenorphine Use in OUD | | | |
|---|---|---|---|
| | International Outpatient Treatment | | |
| Provider Action | WHO[17] | British Columbia[18] | Australia[19] |
| Visit frequency | Not specified | Not specified | • Usually supervised<br>• Takeaways based on stability<br>• Clinical review at least monthly |
| Duration | Recommend against restrictions on duration of Tx | • Longer Tx improves outcomes<br>• Recommend at least 2 years of Tx | • Not a time-limited Tx<br>• The key is stability; there is no reason to encourage medication cessation. |
| Prescription frequency | Not specified | • Not specified<br>• Observed initially until carry privileges earned<br>• No more than 7-day supply as carry | • Not specified<br>• Observed administration until stable enough for takeaways |
| Usual dosing | • Start low<br>• Recommend against restrictions on maximum dosing levels | • 8-12 mg daily<br>• Max 24 mg daily<br>• Every other day dosing recommended | • 12-24 mg daily usual<br>• Rarely 32 mg daily<br>• Max on day 2: 16 mg<br>• Max on day 3: 24 mg<br>• Dose stabilization within 3 days associated with higher retention |
| UDT | System for monitoring safety and risk of diversion | • Baseline; routinely and randomly<br>• Monthly until stable<br>• Quarterly after stable | • Baseline; frequently in beginning and after relapse<br>• Intermittent random screening |
| Pill counts | System for monitoring safety and risk of diversion | Not specified | Not specified |
| PDMP | System for monitoring safety and risk of diversion | Recommended prior to start and routinely | Not specified |

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Guidelines are consistent in recommending urine drug testing (UDT) at baseline and frequently throughout treatment, but they begin to vary in recommendations for additional testing frequency throughout treatment. UDT utilization is readily available in claims data, but these data generally lack information on the outcome and interpretation of UDT. The recommended duration of MAT is relatively consistent across guidelines, where time limits are discouraged and patient preference is emphasized, among other factors. However, longer treatment courses are associated with improved outcomes—one guideline recommends at least 1 year of treatment[14] and another recommends a minimum of 2 years.[18] Follow-up visits and prescription information, including prescribed dose, are readily available in medical and pharmacy claims data that enable tracking of individual patients during treatment. Duration of treatment can be assessed, but accuracy is highly dependent on length of enrollment with a specific payer.

**Table 3**[12-19] examines common elements of nonpharmacologic treatment that are recommended to improve outcomes. Psychosocial interventions and case management are strongly recommended in every guideline. These criteria encompass numerous data elements that are available in claims. The guidelines generally agree that basic needs such as housing, employment, family, and legal concerns can significantly affect treatment and providers should be aware of available community resources. Case management or care coordination services providing assistance are increasingly utilized and/or covered by many benefits providers.[20-22] Although there is consensus regarding the value of psychosocial interventions in treatment, the specific therapies recommended vary considerably. Mutual help or 12-step facilitation

**TABLE 3.** Psychosocial Interventions and Care Coordination in OUD

| Common Elements in MAT Guidelines for Buprenorphine Use in OUD | | | | |
|---|---|---|---|---|
| **Provider Assessment** | **US OBOT** | | | |
| | **ASAM[12]** | **SAMHSA[13,14]** | **VA/DoD[15]** | **FSMB[16]** |
| High risk (OBOT questionable) | • Alcohol use disorder<br>• BZD use<br>• Suicidal/homicidal ideation<br>• May not be suitable for OBOT:<br>› Alcohol use disorder<br>› Sedative, hypnotic, anxiolytic use disorder<br>› High risk of diversion<br>› Stimulant, cannabis, and other drugs not reason to deny Tx | Risk does not preclude Tx:<br>• Alcohol abuse/dependence<br>• BZD or sedative/hypnotic abuse/dependence<br>• Suicidal/homicidal<br>• Significant untreated psychiatric comorbidity | • Pain requiring IR opioids<br>• Many failed attempts at Tx | • Use of sedatives or alcohol<br>• Continue to misuse and experience withdrawal at 32 mg daily<br>• Persistent aberrant behaviors despite adjustments to Tx |
| Psychosocial treatment | Recommended for every patient on MAT:<br>• Individual/couples/group<br>• CBT<br>• CM<br>• Relapse prevention<br>• Motivational interviewing<br>• Mutual help (not equivalent to professional psychosocial Tx) | • Recommended:<br>› Medical management using brief supportive counseling at each visit<br>• Recommended, not required:<br>› Addiction counseling<br>› CM<br>› Motivational interviewing<br>› CBT<br>› Peer support or self-help groups | No Tx can be recommended over another:<br>• Behavioral therapy<br>• CBT<br>• CM<br>• CRA<br>• Motivational enhancement therapy<br>• 12-step facilitation recommended and effective with participation | • Recommended for all patients on MAT<br>• Evidence that MAT + psychosocial Tx is superior to either alone<br>• Regular assessment of patient's level of engagement<br>• Counseling<br>• 12-step facilitation |
| Care coordination/ case management[a] | • Linkages to existing family support systems<br>• Referrals to community-based services:<br>› Employment<br>› Housing<br>› Legal | • Providers should be aware of available community services<br>• Consider referral to social workers or case managers for services:<br>› Employment<br>› Family<br>› Legal<br>› Housing<br>› Medicaid<br>› Food assistance programs | • Social and environmental factors can impact recovery if not addressed<br>• Access to supportive recovery environment:<br>› Housing and social support<br>› Employment<br>› Legal | • Develop recovery support system<br>• Assess changes in social functioning and relationships:<br>› Family/friends<br>› Employment<br>› Housing<br>› Legal |
| Response to relapse | • Increase Tx intensity<br>• Increase/change psychosocial supports | • Plan should be in place for relapse in treatment agreement<br>• Physicians should be familiar with Brief Intervention:<br>› Assess relapse triggers<br>› Social and recovery environment<br>› Insight, motivation, and readiness to change | Adapt Tx to meet patient needs:<br>• Add or substitute another psychosocial or medication intervention<br>• Change intensity with medication or therapy adjustments | Reassess Tx plan; intensify structure and/or intensity of services:<br>• Assess and develop coping skills<br>• Identify and plan for relapse triggers |

ASAM indicates American Society of Addiction Medicine; BZD, benzodiazepine; CBT, cognitive behavioral therapy; CM, contingency management; CRA, community reinforcement approach; Etoh, ethanol/alcohol; IR, immediate release; FSMB, Federation of State Medical Boards; MAT, medication-assisted treatment; OBOT, office-based opioid treatment; OTP, opioid treatment program; OUD, opioid use disorder; SAMHSA, Substance Abuse and Mental Health Services Administration; Tx, treatment; VA/DoD, Veterans Affairs/Department of Defense; WHO, World Health Organization.

[a]The terms *care coordination* and *case management* are used interchangeably in literature and guidelines.

programs are embraced and recommended within some guidelines[14] and not considered equivalent to professional psychotherapy treatment in others.[12] In addition, these groups are anonymous and patient involvement is not visible in claims. Relapse is a critical indicator of successful treatment because OUD is a chronic relapsing disorder, with guideline consensus that treatment should be intensified with adjustments to follow-up frequency, length of prescription renewals, and psychosocial interventions in the event of relapse. Tracking relapse through medical claims data is elusive, but achievable, with accurate definitions of measurable related events captured through intelligent design of analytic engines. After multiple relapses despite treatment adjustments, the appropriate treatment setting may need to be reconsidered along with overall risk status. High-risk MAT patients include those with comorbid alcohol abuse, benzodiazepine use, or

| Common Elements in MAT Guidelines for Buprenorphine Use in OUD | | | |
|---|---|---|---|
| Provider Assessment | International Outpatient Treatment | | |
| | WHO[17] | British Columbia[18] | Australia[19] |
| High risk (OBOT questionable) | Harmful use/dependence | • Alcohol use disorder associated with poor outcomes; assessed and treatment offered<br>• Assess and address behavioral addictions<br>• Unsafe housing<br>• Drug-dealing partner<br>• Poor coping skills | • Polydrug use (Etoh, BZD)<br>• Refer to specialty services if misuse of multiple drugs or alcohol<br>• Significant psychiatric disease favors (OTP) methadone or specialized facility<br>• Consider risk of providing MAT vs relapse in the setting of other drug use |
| Psychosocial treatment | A variety of structured counseling and psychotherapy should be available:<br>• On-site psychiatric and psychosocial services should be available<br>• Supportive counseling | • Combining MAT with psychosocial interventions has led to improved outcomes<br>• Psychosocial interventions include:<br>› Motivational interviewing<br>› CBT<br>› Counseling<br>› Self-help groups<br>› Programs in the community | • First aim is stabilization<br>› Interventions may be delayed until immediate needs are achieved<br>• Interventions may be one-on-one or group:<br>› CBT<br>› CM<br>› Counseling<br>› Self-help group<br>• Promotes treatment compliance |
| Care coordination/ case management[a] | • Links to family and community services<br>• Variety of services should be available:<br>› Housing<br>› Employment<br>› Legal<br>› Welfare | Programs are expected to incorporate a biopsychosocial and spiritual approach to Tx addressing:<br>• Employment<br>• Housing<br>• Legal problems<br>• Poverty<br>• Lack of education<br>• Poor nutrition<br>• Exposure to violence | • Tailored to the individual<br>• First aim of Tx is stabilization, then address:<br>› Social<br>› Housing<br>› Legal<br>› Employment<br>› Mental health |
| Response to relapse | Not specified | Suspend carry privileges | • Review psychosocial interventions<br>• Levels of supervision<br>• Monitoring and review<br>• Dose of substitution medication<br>• Role of adjuvant interventions<br>• Review alternative pharmacotherapies |

ASAM indicates American Society of Addiction Medicine; BZD, benzodiazepine; CBT, cognitive behavioral therapy; CM, contingency management; CRA, community reinforcement approach; Etoh, ethanol/alcohol; IR, immediate release; FSMB, Federation of State Medical Boards; MAT, medication-assisted treatment; OBOT, office-based opioid treatment; OTP, opioid treatment program; OUD, opioid use disorder; SAMHSA, Substance Abuse and Mental Health Services Administration; Tx, treatment; VA/DoD, Veterans Affairs/Department of Defense; WHO, World Health Organization.

[a]The terms *care coordination* and *case management* are used interchangeably in literature and guidelines.

dependence on a sedative, hypnotic, or anxiolytic, due to their additive central nervous system depressant effects and increased risk of overdose.

## DISCUSSION

Any approach to a societal problem as pervasive as the uncontrolled growth of OUD requires access to effective OUD treatment that is guided by the intent to improve and individualize care. As stated by ASAM, "In circumstances in which the *Practice Guideline* is being used as the basis for regulatory or payer decisions, improvement in quality of care should be the goal."[12] Payers, both public and private, have wrestled with the appropriate response to the growing crisis surrounding OUD. Access to care must be assured while mitigating not only excessive healthcare utilization by those engaging in opioid

and other substance abuse, but also the effects of unscrupulous practices and/or providers. In order to appropriately understand and respond to the complex needs of individuals with OUD and deploy evidence-based treatment, health systems must develop the ability to identify and track patients in a highly reliable and reproducible manner.

Individualized care requires payer identification of members; however, evaluation of their healthcare utilization has proven a challenge for federal governmental agencies. Utilization assessment systems have inadequately addressed this problem and have not achieved sufficient granularity to create improved outcomes at the patient level. The Drug Abuse Warning Network system, for instance, has provided population-level data for OUD and motivated policy changes through its final published year in 2011. However, these data were aggregated over several years prior to publication and were therefore descriptive public health metrics, but they lacked the specificity and timeliness needed to affect patient outcomes. Similarly, the National Electronic Injury Surveillance System data set has been used to track adverse drug events, but this system is used to retrospectively query data sets that have been deidentified in order to provide population-level statistics. The NSDUH has been performed since the 1970s and examines population trends in drug abuse, but it cannot be harnessed to individualize treatment. In short, the federal government's tracking systems are designed for trend analysis and are not capable of identifying at-risk patients even if healthcare privacy laws permitted them to act on personally identifiable health information. These limitations have shaped the solutions enacted by the federal government, which focus their efforts on harm-reduction strategies, such as syringe service programs, naloxone distribution, treatment coordination, expanding treatment capacity for OUD, and encouraging the use of opioid prescribing guidelines.

Although visibility of claims data may be limited to individual payers for privacy reasons, the proposed outcomes presented herein are consistent with the evaluation criteria set forth by the National Quality Forum (NQF) for healthcare performance measures.[23] Buprenorphine-specific NQF measures include measurement of adherence and access to buprenorphine for OUD. We incorporated these measures and expanded our analyses to include relapse, treatment adherence, psychosocial interventions, case management, high-risk patients, and buprenorphine dose. The relative importance of these outcomes varies; for example, signs of quality treatment would include consistent patient adherence to follow-up (demonstrating treatment stability with their provider), incorporating psychosocial interventions, and providing care coordination services. However, the utility of these outcome measures is somewhat dependent on the presence or absence of relapse, because these outcomes provide insight into potential causes of relapse or areas where treatment may need to be adjusted to decrease the rate of relapse. One might imagine having the ability to compare providers by the relapse rate of their practice. Such a measurement is considerably more meaningful than arbitrary rating systems or risk reports and may assist payers in decreasing practice variation by preferentially routing patients to higher-quality providers, who may then be rewarded with preferred provider status and reimbursement. Not only would this identify higher-quality providers, but underperforming providers would be incentivized to focus on practice improvement to qualify for inclusion and decrease punitive or costly remediation.

When searching for answers to high rates of relapse despite adjustments in treatment, the high-risk criteria begin to provide insight into potential reasons for this pattern by identifying the highest-risk patients. Revisiting risk assessment in this manner may help providers determine which patients may not be appropriate for OBOT and for whom referral to a more intensive treatment program may be necessary to address their individual needs. Similarly, the buprenorphine dose criteria identify high-dose prescribing of buprenorphine, which is controversial. Payers can utilize this information to identify unscrupulous prescribers who are clear outliers, with the majority of their patients receiving high-dose buprenorphine, potentially indicating "pill mill" operations. By evaluating the treatment patterns and outcomes of all insured members within a provider's patient panel, quality assessment and comparison among healthcare providers becomes a reality.

### Limitations

There are several notable limitations to this type of analysis. The limitations of utilizing medical and pharmacy claims data to measure healthcare quality are well known and include reliance on correct coding of medical claims and that detection is restricted to enrolled members, which may not accurately reflect use of secondary insurance or cash pay for healthcare services or prescriptions.

## CONCLUSIONS

This paper presents a consolidation of the evidence base for treatment of individuals with OUD in the OBOT setting. It is an outline of common elements among guidelines that, when linked with claims data, could be used to create a framework to follow patients and tailor proprietary solutions in order to provide better care and outcomes for these individuals. The opioid crisis continues to change, characterized by a shift away from prescription abuse toward illicit opioid abuse, driving the increases in opioid overdose deaths and increasing rates of OUD.[5] This change therefore requires a paradigm shift in treatment strategy, as efforts to educate stakeholders, restrict prescribing, and legislate solutions to reduce prescription opioid abuse will all be less effective when attempting to address illicit abuse. We propose that any viable solution must be capable of tracking individuals who are engaging in opioid abuse or have diagnosed OUD, facilitate access to high-quality providers through outreach and care coordination, and prospectively measure treatment outcomes for these patients. Only payers have the permitted access to individual claims data and the authority to control reimbursement with their strategic healthcare partnerships. All other stakeholders should consider

supporting their efforts through tax incentives and grant funding where possible. ■

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**eAppendix.** Data Analytics Comparison: PMP vs Claims Data

State prescription monitoring programs (PMPs) are the only functioning government surveillance systems capable of reporting individual prescription data for timely intervention upon request of an authorized provider. State PMPs are now commonly providing prescribers individualized reports of their prescribing habits including the potential for alerts of behavior suggestive of doctor shopping. A PMP's strength, however, is the comprehensive reporting of controlled substances (required by legal statute) with potential detection of multiple providers or pharmacies and simple reporting of total morphine equivalent daily dose (MEDD), which potentially captures data across multiple payers or providers. Even in this limited role, PMP results cannot differentiate use, misuse, or abuse and are affected by changes in address, exchange agreements between states, and in many cases cannot capture short-term supplies, or MAT from OTPs or intensive addiction treatment centers. In contrast, claims data includes medical consults, office visits, lab tests, all prescription information (not just controlled substances), including emergency services, hospital or addiction admissions where misuse and abuse are confirmed and reported by healthcare providers. Developing novel methods of merging these data sources and correlating their findings with a consolidation of the guidelines for appropriate evaluation and treatment of individuals with OUD presents a new avenue for solving some of the challenges inherent to treating this population.

Payers can utilize analytics to create a surveillance program capable of detecting opioid abuse and related emergency services, emergency department visits, hospital admissions, and intensive care unit (ICU) stays at an individual level. Successful detection allows responsible stewardship and improved awareness through notification of key members of an insured individual's health care team, who are already authorized to access health information, including notifying opioid or MAT prescribers of serious events that may significantly inform prescriber decision making. In addition to state-of-the-art automated care coordination, the facilitation of improved access to high quality providers begins with measuring the common elements that represent best practice in available medical and pharmacy claims data. From these data, a treatment pattern begins to emerge for each individual patient allowing measurement of important outcomes. Overall claims data provides a more comprehensive window into an individual's treatment that can be correlated with meaningful outcomes as quality indicators of best practice implementation. By evaluating the treatment patterns and outcomes of all insured

members within a provider's patient panel, quality assessment & comparison between healthcare providers becomes a reality.