

Proposed New Measure for HEDIS^{®1} 2020: Pharmacotherapy for Opioid Use Disorder (POD)

NCQA seeks public comment on a proposed new measure for potential inclusion in the HEDIS 2020 measurement set:

- *Pharmacotherapy for Opioid Use Disorder*: The percentage of new opioid use disorder (OUD) pharmacotherapy episodes that resulted in 180 or more covered treatment days among members 16 years of age and older with a diagnosis of OUD.

Literature suggests that pharmacotherapy can improve outcomes for individuals with OUD and that continuity of pharmacotherapy is critical to prevent relapse and overdose.^{2,3,4} However, despite the evidence and recommendations of clinical practice guidelines, pharmacotherapy is an underutilized treatment option for individuals with OUD. To address this gap in care, NCQA identified a measure concept that identifies new episodes of OUD pharmacotherapy and assesses adherence to treatment.

NCQA's long-standing measure *Initiation and Engagement of Alcohol and Other Drug Abuse or Dependence Treatment (IET)* assess initiation of treatment within 14 days following a new episode of alcohol or other drug abuse and dependence, and ongoing engagement in treatment within the 34 days following initiation. *Pharmacotherapy for Opioid Use Disorder* will complement IET and together they will assess pharmacotherapy for members with a diagnosis of OUD.

The measure concept was adapted from an existing measure—Continuity of Pharmacotherapy for Opioid Use Opioid (NQF #3175)—developed by RAND and stewarded by the University of Southern California (USC). The measure assesses the percentage of adults who receive OUD pharmacotherapy and adhere to continuous treatment for at least 180 days, allowing for 7 treatment gap days. RAND and NCQA maintain mutual interest in the measure concept being adapted for use in HEDIS.

NCQA field-tested a version of the RAND measure in fall 2018 using Medicare, commercial and Medicaid managed care claims data. The NCQA version of the RAND measure included two major adaptations: 1) a focus on “new,” or incident episodes of OUD pharmacotherapy, and 2) the inclusion of adolescents 16 and 17 years of age, for whom certain OUD pharmacotherapies have been FDA-approved to treat OUD, and the inclusion of older adults (65 and older).

Field-testing demonstrated that the measure can be feasibly calculated at the health-plan level of accountability, with a sufficient denominator size for HEDIS reporting. Testing also demonstrated variation in performance, both within and across product lines, which suggests a significant gap in care and room for improvement. Average plan-level performance indicated that 25.0% of new OUD pharmacotherapy episodes within the Medicare population, 22.6% of new OUD pharmacotherapy episodes within the commercial population and 33.1% of new OUD pharmacotherapy episodes within the Medicaid managed care population resulted in 180 or more treatment days.

¹ HEDIS[®] is a registered trademark of the National Committee for Quality Assurance (NCQA).

² National Institute on Drug Abuse. 2016. *Effective Treatments for Opioid Addiction*. <https://www.drugabuse.gov/effective-treatments-opioid-addiction-0>

³ Pew. 2016. *Medication-Assisted Treatment Improves Outcomes for Patient with Opioid Use Disorder*. <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/11/medication-assisted-treatment-improves-outcomes-for-patients-with-opioid-use-disorder#1-background>

⁴ Department of Health and Human Services. 2016. *Medicare Coverage of Substance Abuse Services*. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1604.pdf>

NCQA seeks general feedback on the new measure and on the following questions:

1. Of the three FDA-approved medications for the treatment of OUD, only buprenorphine and buprenorphine combination products have been approved for use among adolescents under the age of 18. Buprenorphine is FDA-approved for treatment of those 16 and older. To assess the quality of treatment among all members for whom OUD pharmacotherapy is appropriate, NCQA and members of our advisory panels recommend that this measure include members 16 and older. NCQA seeks feedback on the inclusion of adolescents 16 and 17 years of age in the eligible population of this measure.
2. As specified, this measure aims to assess continuation of OUD pharmacotherapy among a population experiencing a new or incident episode of pharmacotherapy. This decision was based on early feedback from our measurement advisory panels and stakeholders who suggested that there is a need to capture early adherence to newly dispensed-pharmacotherapy among a population that often stops and reinitiates treatment. Consistent with the approach taken in other HEDIS measures, the identification of a “new” episode requires the use of a negative look-back period, during which a member in the denominator must not have a covered day of OUD pharmacotherapy. The current measure uses a 15-day negative look-back period and aims to balance identification of “new” episodes with a plan’s ability to report a sufficient denominator size. NCQA seeks feedback on the proposed look-back period.
3. Currently in the United States, methadone for treatment of OUD can only be administered in opioid treatment programs (OTP). NCQA recognizes the current challenges surrounding the use of administrative billing codes to calculate covered treatment days for this measure, as these codes are often not used for daily billing and do not include the medication days’ supply. NCQA seeks feedback on both the current list of administrative billing codes included in the measure and the proposed days’ supply for each code (**Appendix A**).
4. The population captured in this measure have high utilization of acute care services such as hospitalizations. During development, a suggestion was made that members who are hospitalized during their adherence period should either be removed from the measure denominator or should have their adherence “paused” until they are discharged from their stay. NCQA seeks feedback on specifying the measure to exclude hospitalization stays or “pause” the adherence calculation.
5. As specified, this measure requires both a medical and a pharmacy benefit. NCQA seeks feedback on the potential requirement of a chemical dependency benefit, given the ability to provide evidence-based treatment for OUD in an office-based setting.

Supporting documents include the draft measure specification and evidence workup.

**NCQA acknowledges the contributions of the Geriatric Measurement Advisory Panel,
Behavioral Health Measurement Advisory Panel and Technical Measurement Advisory Panel**

Appendix A: OUD Medication Treatment Codes				
HEDIS Value Set⁵	Code System	Code	Description	Proposed Days Supply/Days Covered
OUD Medication Treatment 1 Day Supply	HCPCS	H0020	Alcohol and/or drug services; methadone administration and/or service (provision of the drug by a licensed program)	1
	HCPCS	H0033	Oral medication administration, direct observation	
	HCPCS	J0571	Buprenorphine, oral, 1 mg	
	HCPCS	J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine	
	HCPCS	J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine	
	HCPCS	J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine	
	HCPCS	J0575	Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine	
	HCPCS	S0109	Methadone, oral, 5 mg	
OUD Medication Treatment 31 Days Supply	HCPCS	Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	31
	HCPCS	Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	
	HCPCS	J2315	Injection, naltrexone, depot form, 1 mg	
OUD Medication Treatment 180 Days Supply	HCPCS	J0570	Buprenorphine implant, 74.2 mg	180

⁵ These HEDIS Value Sets included in the HEDIS Value Set Directory (VSD) were developed by and are owned by the National Committee for Quality Assurance (NCQA). NCQA holds a copyright in the HEDIS VSD and may rescind or alter the HEDIS VSD at any time. Users shall not have the right to alter, enhance or otherwise modify the HEDIS VSD, and shall not disassemble, recompile or reverse engineer the HEDIS VSD. Anyone desiring to use or reproduce the HEDIS VSD without modification for an internal non-commercial purpose may do so without obtaining any approval from NCQA. All other uses, including a commercial use and/or external reproduction, distribution or publication must be approved by NCQA and are subject to a license at the discretion of NCQA. The HEDIS VSD is provided "as is" without warranty of any kind. The HEDIS VSD contains proprietary code values owned by third parties that are protected under federal copyright laws. All uses of the third-party codes may require a license from the copyright owner. NCQA disclaims all liability for use of the third-party codes.

Pharmacotherapy for Opioid Use Disorder (POD)

SUMMARY OF CHANGES TO HEDIS 2020

- First-year measure.

Measure Description

The percentage of new pharmacotherapy treatment episodes that resulted in 180 or more covered treatment days among members age 16 and older with a diagnosis of opioid use disorder (OUD).

Measure Definitions

Intake period A 12-month window that begins on July 1 of the year prior to the measurement year and ends on June 30 of the measurement year.

New episode of OUD pharmacotherapy A dispensing event where the member did not have any active prescriptions for OUD pharmacotherapy during the 15 days prior to the dispensing event.

Active prescription A prescription is considered active if the “days supply” indicated on the date when the member filled the prescription is the number of days or more between that date and the relevant service date.

Calculating calendar days covered by OUD pharmacotherapy If multiple prescriptions for the same or different medications are dispensed or administered on the same day or on different days, with overlapping days supply, sum the days’ supply using the following rules to calculate the calendar days covered by OUD pharmacotherapy.

- For multiple dispensing events or medication treatment events for the same or different medications on the same day, use the longest days supply.
- For multiple dispensing events or medication treatment events for different medications on different days, with overlapping days supply, count each day within the treatment period only once.
- For multiple prescriptions for the same medication dispensed on the same day or on different days, with overlapping days supply, sum the days supply and use the total.

Subtract any days supply that extends beyond December 31 of the measurement year.

Use the Drug ID field in the Medication List Directory of NDC codes and the provided value set descriptions to determine if the prescriptions are the same or different.

Eligible Population

Note: Members in hospice are excluded from the eligible population. Refer to General Guideline 20: Members in Hospice.

Product lines	Commercial, Medicaid, Medicare (report each product line separately).
Ages	16 years and older as of December 31 of the measurement year. Report three age stratifications and total rate. The total is the sum of the age stratifications. <ul style="list-style-type: none"> • 16–64 years. • 65 years and older. • Total.
Continuous enrollment	15 days prior to the New Episode of OUD Pharmacotherapy through 179 days after the New Episode of OUD Pharmacotherapy (195 total days).
Allowable gap	None.
Anchor date	None.
Benefits	Medical and pharmacy.
Event/diagnosis	Follow the steps below to identify eligible events. <p>Step 1 Identify members with any diagnosis of opioid use disorder (<u>Opioid Abuse and Dependence Value Set</u>) during the Intake Period.</p> <p>Step 2 For each member, identify all dispensing events or medication treatment events for OUD medication treatment during the Intake Period. <ul style="list-style-type: none"> • <u>Opioid Use Disorder Treatment Medications List</u>. • <u>Opioid Use Disorder Medication Treatment 1 Day Supply Value Set</u>; <u>Opioid Use Disorder Medication Treatment 31 Days Supply Value Set</u>; <u>Opioid Use Disorder Medication Treatment 180 Days Supply Value Set</u>. </p> <p>Step 3 Identify new episodes of OUD pharmacotherapy.</p> <p>For the first dispensing event during the Intake Period, identify if the member had a previous OUD pharmacotherapy dispensing event (<u>Opioid Use Disorder Treatment Medications List</u>) or medication treatment event (<u>Opioid Use Disorder Medication Treatment 1 Day Supply Value Set</u>; <u>Opioid Use Disorder Medication Treatment 31 Days Supply Value Set</u>; <u>Opioid Use Disorder Medication Treatment 180 Days Supply Value Set</u>) where days supply extends into the 15 days prior to the dispensing event.</p> <p>For example, for a pharmacotherapy dispensing event on July 1 of the year prior to the measurement year, if the member had a medication treatment event on December 20, two years prior to the measurement year, with a 180 days supply, the member had an active prescription during the 15 days prior to the dispensing event (June 16–30) and the July 1 dispensing event is not a new episode.</p> <p>For subsequent dispensing events, use calendar days covered by OUD pharmacotherapy to identify new episodes. Any event preceded by 15 calendar days not covered by OUD pharmacotherapy is considered a new episode.</p> <p>Step 4 Identify calendar days covered by OUD pharmacotherapy. For dispensing events (identified in step 3) use days supply from the pharmacy data. For medication treatment events (identified in step 3) use the days supply in the value set name.</p>

Step 5 Calculate continuous enrollment. The member must be continuously enrolled (without a gap in coverage) from 15 days prior to the New Episode of OUD Pharmacotherapy through 179 days after the New Episode of OUD Pharmacotherapy (195 total days).

Note: All episodes that were not excluded remain in the denominator. The denominator for this measure is based on episodes, not on members.

Administrative Specification

Denominator The eligible population.

Numerator At least 173 days of treatment with OUD pharmacotherapy, beginning on the New Episode of OUD Pharmacotherapy date through 179 days after the New Episode of OUD Pharmacotherapy date (180 total days). This allows a gap in medication treatment up to a total of 7 days during the 180-day period.

Identify calendar days covered by OUD pharmacotherapy, beginning on the New Episode of OUD Pharmacotherapy date through 179 days after the New Episode of OUD Pharmacotherapy date (180 total days).

For dispensing events (Opioid Use Disorder Treatment Medications List), use days supply from the pharmacy data.

For medication treatment events (Opioid Use Disorder Medication Treatment 1 Day Supply Value Set; Opioid Use Disorder Medication Treatment 31 Days Supply Value Set; Opioid Use Disorder Medication Treatment 180 Days Supply Value Set), use the days supply in the value set name.

Opioid Use Disorder Treatment Medications

Description	Prescription
Antagonist	<ul style="list-style-type: none"> Naltrexone (oral and injectable)
Partial agonist	<ul style="list-style-type: none"> Buprenorphine (sublingual tablet, injection, implant) Buprenorphine/naloxone (sublingual tablet, buccal film, sublingual film)

Note: Methadone is not included on the medication lists for this measure. Methadone for OUD is only administered or dispensed by federally certified opioid treatment programs (OTPs) and does not show up in pharmacy claims data. A pharmacy claim for methadone would be more indicative of treatment for pain than for an OUD; therefore, it is not included on the medication lists. The Opioid Use Disorder Medication Treatment 1 Day Supply Value Set includes codes that identify methadone treatment because these codes are used on medical claims, not on pharmacy claims.

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table OHD-1/2/3: Data Elements for Adherence to Pharmacotherapy for Opioid Use Disorder

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	<i>For each age stratification and total</i>
Number of required exclusions	<i>For each age stratification and total</i>
Numerator events by administrative data	<i>For each age stratification and total</i>
Numerator events by supplemental data	<i>For each age stratification and total</i>
Reported rate	<i>For each age stratification and total</i>

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Pharmacotherapy for Opioid Use Disorder (POD)

Measure Workup

Topic Overview

Prevalence and Importance

In 2016, 20.1 million U.S. residents age 12 and older (7.5% of the population) were classified as having a substance use disorder (SUD) within the past year (SAMHSA, 2017). SUD is defined as recurrent use of alcohol and/or drugs that causes significant clinical and functional impairment (SAMHSA, 2015d). In 2016, over 2 million U.S. residents 12 years of age and older had an opioid use disorder (OUD) (SAMHSA, 2017). OUD includes recurrent use and desire for opioids despite both functional and clinical interference (SAMHSA, 2015d). OUD can be mild, moderate or severe, according to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) (SAMHSA, 2015d).

While the prevalence of SUD in the U.S. has remained relatively steady since 2010, the prevalence of nonmedical prescription OUD among adults increased between 2001 and 2013 from 1.4% to 2.1% (Lipari, 2017; Saha, 2017). Today in the U.S., drug overdose is the leading cause of injury, and prescription and illicit opioids are the driver behind the majority of drug overdose deaths (CDC, 2017). Opioid-related overdose deaths in the U.S. increased more than five-fold between 1999 and 2016 (CDC, 2017). In 2016, more than 63,600 deaths were due to drug overdose; of those, 66% involved an opioid (CDC, 2017).

Medication-assisted treatment (MAT) is defined as the use of pharmacotherapy in conjunction with psychosocial interventions (e.g., cognitive behavioral therapy, counseling) for the treatment of individuals with OUD and alcohol use disorder (AUD) (SAMHSA, 2015b). Currently, three drugs are approved by the U.S. Food & Drug Administration for the treatment of OUD: buprenorphine, methadone and naltrexone (FDA, 2018). Use of pharmacotherapy in the treatment of individuals with OUD has been proven to facilitate recovery and improve outcomes (achievement of opioid abstinence, reduction in opioid-related mortality) and is supported by clinical practice guidelines (**Appendix A**).

Specifically, among individuals with OUD, 26% engage in any treatment and 19% engage in OUD-specific treatment (Wu, 2016). Current literature suggests that fewer than 40% of U.S. residents over the age of 12 with an OUD diagnosis receive pharmacotherapy (Volkow, 2014). Further, the proportion of individuals with a treatment plan for OUD diagnosis that includes pharmacotherapy declined between 2002 and 2012 (from 35% of opioid treatment admissions to 28%) (NIDA, 2016). Impediments to the use of pharmacotherapy include gaps between treatment need and provider capacity, insurance coverage and reimbursement, stigma and bias against pharmacotherapy use and access to providers and treatment facilities (Jones et al., 2015; ASAM, 2016).

Health importance

Individuals with OUD are at increased risk of death, opioid-related overdose, emergency department visits and readmissions and blood-borne infectious disease (NASEM, 2017). Use of and adherence to appropriate evidence-based treatment for OUD has been shown to improve outcomes for patients and reduce the burden on the health care system by preventing acute exacerbations and emergencies (CDC, 2018).

Individuals with OUD who engage in treatment with pharmacotherapy are less likely to exhibit withdrawal or craving symptoms and use illicit opioids, and are more likely to remain in treatment and engage in mental health therapy than individuals receiving treatment that does not include medication (NIDA, 2016; Connery, 2015). The benefits of MAT for individuals with OUD extends beyond the reduction of substance use, overdose and mortality to include reduced crime and recidivism, reduced risk of infectious disease and improved patient function (Pew, 2016).

Treatment and Opportunities for Improvement

Available medications and care settings

Three pharmacotherapies are approved by the Food & Drug Administration for treatment of opioid dependence: buprenorphine, methadone and naltrexone (FDA, 2018).

Methadone is a complete opioid agonist that works by completely activating the mu-receptor and eliminating withdrawal symptoms and cravings (NIDA, 2018a). Currently, treatment of patients under 18 requires permission from a legal guardian and evidence that other treatments used to treat OUD have failed (Krambeer, 2001). Methadone is only dispensed in federally approved Opioid Treatment Programs (OTP) that provide comprehensive treatment services, including psychotherapy, for individuals with SUD (ASAM, 2014).

Buprenorphine is a partial opioid agonist that reduces an individual's withdrawal symptoms and cravings (NIDA, 2018a). Buprenorphine, alone and in combination with naloxone, is indicated for individuals 16 and older (Ling, 2012; Chang, 2018). It can be administered and prescribed in OTPs, as well as by any licensed physician in an office setting who has a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) (Alderks, 2017; ASAM, 2014; SAMHSA, 2016a). Office-based opioid treatment (OBOT) is a growing treatment model that integrates SUD treatment into general medical and psychiatric care (ASAM, 2014). OBOTs allow primary care physicians to provide SUD services in their practice settings and expands the availability of pharmacotherapy for the treatment of OUD and AUD.

Naltrexone is a complete opioid antagonist; unlike methadone and buprenorphine, it does not contain any opioid ingredient in its formulation (NIDA, 2018a). Naltrexone prevents an individual from experiencing the intended effects of opioids, such as euphoria, and has been found to be effective in preventing relapse (NIDA, 2018a). Because naltrexone is not considered a scheduled drug, it can be prescribed by any provider licensed to prescribe medications (e.g., physician, physician assistant, nurse practitioner), increasing its availability in multiple care settings (SAMHSA, 2016b; Alderks, 2017).

Despite the minimum age requirements for the three OUD treatment medications, the American Academy of Pediatrics recommends that they be considered for use in the treatment of adolescent and young adult patients with severe OUD (**Appendix A**).

Adherence to treatment

OUD is recognized as a chronic and relapsing disease that should be iteratively managed over the course of a patient's treatment (Kampman, 2015). Use of and adherence to pharmacotherapy in the treatment of OUD has been found to significantly reduce opioid use by minimizing cravings and withdrawal symptoms (SAMSHA, 2015a). Current evidence and clinical recommendations do not specify an ideal or maximum length of pharmacotherapy treatment (**Appendix A**). Clinical efficacy trials used for FDA approval of buprenorphine and naltrexone utilized a 6-month treatment period (FDA, 2016; FDA, 2010). For methadone, guidelines recommend treatment for a minimum of 12 months (NIDA, 2018c).

In 2018, the FDA released a recommendation statement for expansion of clinical trial endpoints used in efficacy trials for the three OUD treatments. The current endpoint used to establish efficacy is a decrease in drug use, but moving forward, trials should also consider mortality, hepatitis C seroconversion, change in disease status and patient-reported outcomes related to patient functional status (FDA, 2018).

A treatment plan including pharmacotherapy must be of adequate duration to be effective. Patients who receive treatment with pharmacotherapy for fewer than 90 days have not shown improved outcomes, compared with those who receive longer-term treatment (HHS, 2016). One study showed that individuals who were noncompliant with their buprenorphine treatment (defined as more than 7 days of missed medications within the initial 4-week period) were 10 times more likely to relapse than those who were compliant (Tkacz, 2012).

Experts have compared the success of pharmacotherapy in the treatment of OUD to other chronic conditions such as diabetes and asthma (McClellan, 2010). Relapse among individuals with OUD is high and has been shown to differ among those who have been treated with and without pharmacotherapy. One randomized effectiveness trial of extended-release, injectable naltrexone found that 1- and 6-month relapse rates were significantly higher among patients who did not engage in treatment using medication than among those who used medication (Nunes, 2018).

The construct of “iterative relapse” or “noncompliance” is common not just for OUD, but across many chronic diseases such as diabetes and asthma. It is estimated that adherence to therapy for many chronic illnesses is around 50%, and often lower among patients with lower socioeconomic status or limited resources and social supports (Martin, 2018).

Coverage

There are wide disparities in coverage and reimbursement policies for treatment of OUD, including pharmacotherapy, across payer types and location. Payers are uniquely positioned to address treatment of OUD through their policies, including drug formularies, prior authorization criteria and reimbursement structure. Literature suggests that Medicaid and state policies that improve pharmacotherapy reimbursement are associated with increased use of pharmacotherapy (Heinrich, 2014).

Currently, Medicaid programs in all 50 states require coverage for at least one of the three FDA-approved OUD medications, and most programs cover all three (KFF, 2018). Buprenorphine is the most widely available, followed by naltrexone and methadone (KFF, 2018).

Among commercial health plans, coverage for the treatment of OUD using pharmacotherapy increased between 2003 and 2014 (Reif, 2017). Using data from a nationally representative survey of commercial health plans, nearly universal coverage of pharmacotherapy was observed in 2014, with little to no variation observed between health plans that had external and internal contracting arrangements for behavioral health and substance use (Reif, 2017). However, despite an overall decrease in the use of prior authorizations since 2003, in 2014, about one third of commercial plans still required prior authorizations for treatment of members with OUD (Reif, 2017).

For Medicare, prescription drugs dispensed for treatment of OUD are covered under Medicare Part D (DHHS, 2016; SAMHSA, 2015a). With the passing of the recent “SUPPORT for Patients and Communities Act,” in October 2018 Medicare will be required to begin paying a bundled rate for pharmacotherapy delivered or prescribed in an OTP on January 1, 2020 (H.R.6, 2018).

Gap in care and disparities

Approximately 25% of individuals engaged in SUD treatment report that their OUD is not addressed (Wu, 2016). This gap in care indicates that despite receiving treatment for other SUDs or health concerns, OUD is not always recognized or prioritized for treatment. Treatment programs have been hesitant to provide pharmacotherapy for OUD (Pew, 2016). Few publicly funded and private-sector treatment programs offer pharmacotherapy to treat substance use disorders (Pew, 2016).

Access to pharmacotherapy for the treatment of OUD remains limited, especially in rural communities (DeFlavio, 2015). In 2011 approximately 43% of U.S. counties had no physicians who could prescribe buprenorphine (Stein, 2015). Even in situations where providers have the authority to prescribe buprenorphine for OUD, the majority are not prescribing at their maximum capacity (Sigmon, 2015). Impediments to increased prescribing have been found to be related to concerns about managing patients with OUD, use of pharmacotherapy and diversion of supplied medications (Huhn, 2017).

Although use of pharmacotherapy in the treatment of OUD is low across all populations, several populations are particularly vulnerable to negative opioid-related outcomes due to lack of treatment, including pregnant and postpartum women; people with psychiatric comorbidities; individuals with a history of interaction with law enforcement or who have recently been released from incarceration; and the elderly (NAP, 2018). Additionally, adolescents, uninsured individuals, African Americans and other minority populations (native Hawaiian, Pacific Islanders, Asian American) have been found to have lower odds of using OUD treatment (Wu, 2016).

Implications

Financial importance

Total overall costs of substance misuse and substance use disorders in the U.S., including loss of work productivity, direct health care expenditures and crime-related costs, exceed \$400 billion annually (HHS, 2016). In 2013, the total cost of prescription opioid use disorders and overdoses was estimated at \$78 billion, with only 3.6% attributable to OUD treatment (NIDA, 2018b).

Use of pharmacotherapy in the treatment of OUD can reduce health care costs and other expenditures. Conservative estimates suggest that for every dollar invested in addiction treatment programs, between \$4 and \$7 are directly returned in decreased drug-related crime, criminal justice costs and theft (NIDA, 2018b). The economic cost-benefit ratio for methadone maintenance therapy has been estimated at nearly \$38 saved for every dollar spent, which considers the impact of unemployment, incarceration, criminal activity, health care utilization and the need for multiple treatment episodes (Legal Action Center, 2015).

Treatment with methadone and buprenorphine has been associated with lower health care expenditures per month than nonmedication behavioral health treatment episodes (ASAM, 2016). The average cost of one year of methadone maintenance treatment is less than \$5,000 dollars per patient (ASAM, 2016).

Appendix 1 outlines available evidence-based guidelines for the treatment of OUD using pharmacotherapy. **Table 1** includes a complete list of FDA-

Guidelines Supporting Pharmacotherapy for OUD

Appendix 1 outlines available evidence-based guidelines for the treatment of OUD using pharmacotherapy. **Table 1** includes a complete list of FDA-approved and guideline-recommended pharmacotherapy for use in the treatment of OUD.

Table 1: Guideline-Recommended and FDA-Approved Pharmacotherapy for Use in Treatment of Opioid Abuse and Dependence

Drug	Route of Administration
Methadone	Oral
Buprenorphine	Sublingual tablet and implant
Buprenorphine/naloxone	Sublingual tablet, buccal film, sublingual film
Naltrexone	Oral and injectable

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Appendix A: Specific Guideline Recommendations

Organization & Year	Guideline Summary	Guideline Citation	Guideline Rating
VA/DoD 2015	<ul style="list-style-type: none"> For patients with opioid use disorder, one of the following medications should be offered as treatment (buprenorphine/naloxone; methadone in an Opioid Treatment Program). [Strong For] For patients with opioid use disorder for whom opioid agonist treatment is contraindicated, unacceptable, unavailable, or discontinued, and who have established abstinence for a sufficient period of time should be offered extended-release injectable naltrexone. [Strong For] 	<p>Department of Veteran Affairs (VA), Department of Defense (DoD): Management of Substance Use Disorders Work Group. (2015). VA/DoD clinical practice guideline for the management of substance use disorders. Version 3.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2015 Dec. 169 p. [327 references]. Retrieved from https://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf</p>	<p>[Strong for] The Work Group is highly confidence that desirable outcomes outweigh undesirable outcomes.</p>
ASAM 2015	<ul style="list-style-type: none"> Methadone and buprenorphine are recommended for opioid use disorder treatment and withdrawal management. Naltrexone (oral; extended-release injectable) is recommended for relapse prevention. 	<p>Kampman, K., Jarvis, M. (2015). American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. <i>Journal of Addiction Medicine</i>; 9(5): 358–367. DOI: 10.1097/ADM.000000000000166.</p>	<p>All statements required to meet criteria for both appropriateness and necessity as defined by expert group.</p> <p>Appropriateness was defined as “a statement, procedure or treatment is considered to be appropriate if the expected health benefit) e.g. increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences (e.g. mortality, morbidity, anxiety, pain) by a sufficiently wide margin that the procedure is worth doing, exclusive of cost.”</p> <p>A statement was considered necessary when all the following criteria were met:</p> <ol style="list-style-type: none"> 1. It would be considered improper care not to provide this service 2. Reasonable chance exists that this procedure and/or service will benefit the patient 3. The benefit to the patient is of significance and certainty

Organization & Year	Guideline Summary	Guideline Citation	Guideline Rating
<p>APA 2006</p>	<ul style="list-style-type: none"> • Methadone and buprenorphine are recommended for patients with opioid dependence [I]. Naltrexone is an alternative strategy [I]. 	<p>American Psychiatric Association: Work Group on Substance Use Disorders. (2006). Practice Guideline for the Treatment of Patients With Substance Use Disorders Second Edition. American Psychiatric Association (APA); 2006 Aug. 276 pg. [1789 references]. Retrieved from https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/substanceuse.pdf</p>	<p>[I] Recommended with substantial clinical confidence.</p>
<p>AAP 2016</p>	<ul style="list-style-type: none"> • Pediatricians should consider offering medication-assisted treatment to their adolescent and young adult patients with severe opioid use disorders. 	<p>American Academy of Pediatrics. (2016). Medication-Assisted Treatment of Adolescents With Opioid Use Disorders. Retrieved from http://pediatrics.aappublications.org/content/early/2016/08/18/peds.2016-1893.</p>	<p>Not graded</p>