

The Role of Managed Care Professionals and Pharmacists in Combating Opioid Abuse

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The Economic Impact of Opioid Abuse in the United States

The overall undesirable health burden of the misuse of prescribed opioid agents has been documented extensively in terms of drug abuse, dependence, and overdose. However, it can be very difficult to develop optimal policies to address this burden while balancing the needs of patients who need treatment for pain. Strategies to do so must be both clinically appropriate and cost-effective. One important factor in addressing the opioid crisis is addressing the economic burden that results from adverse events (AEs) and poor health outcomes related to opioid abuse and misuse in the United States. One landmark study in this area was performed by Florence et al, covering the economic burden created by opioid misuse/abuse in the calendar year 2013. In this analysis, the investigators calculated cost estimates of prescription opioid overdose, abuse, and dependence based on the incidence of deaths related to overdose and the prevalence of abuse and dependence over the 2013 1-year time period. This was approached from a societal perspective, addressing the costs for those who experienced overdose or abuse and dependence and societal costs, including those related to criminal-justice actions. The actual costs for abuse and dependence were overall annual costs in this study, while those for fatalities were lifetime costs discounted to the 2013 value at a 3% rate. If the most recent year of data used was before 2013, the costs were adjusted for inflation to 2013 dollars. Fatality data were obtained from the National Vital Statistics System, with prevalence data on abuse/dependence from the National Survey of Drug Use. Cost data were derived from several sources, including healthcare claims data from the Truven Health MarketScan Research Databases, with costs of fatalities from Web-based Injury Statistics Query and Reporting System cost module. Criminal-justice costs arose from the Justice Expenditure and Employment Extracts published by the Department of Justice. Lost productivity estimates were adapted from a previous study.¹

Results demonstrated that the aggregate costs associated with cases of opioid abuse/dependence and fatal overdose were over \$78.5 billion, with a range of \$70.1 billion to \$87.3 billion. Nearly two-thirds of the total costs were attributed to healthcare, substance

ABSTRACT

Substance misuse is a critical and costly public health problem in the United States. Data as of 2016 show 11,517 cases of opioid analgesic misuse, with the majority (6924 cases) related to hydrocodone misuse. Substance misuse impacts our society significantly with high costs related to healthcare, crime, and lost productivity. Opioid analgesic pain relievers are one of the most prescribed classes of medications and are among the most common drugs related to misuse. Increases in emergency department visits of over 200% have been associated with a dramatic surge in written prescriptions for opioid pain relievers. Mortality with opioid misuse has increased dramatically, with 2016 statistics demonstrating 42,249 deaths from any opioid; 15,469 heroin-related deaths; 14,487 deaths related to natural and semi-synthetic prescription agents; 19,413 deaths caused by mainly illicit use of synthetics (mostly fentanyl); and 3373 deaths related to methadone use. Per the Centers for Disease Control and Prevention (CDC), 3 of 5 drug overdoses are from an opioid, such as heroin, morphine, and prescription pain relievers. In addition, the expenses associated with drug use disorders are comparable to the costs of other chronic diseases, such as diabetes. Policymakers, criminal justice officials, and healthcare providers consider illicit drug and opioid misuse a national epidemic that must be addressed more strongly to improve pain management in the United States, optimize patient outcomes, and decrease unlawful drug use for pain relief.

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abuse treatment, and lost productivity (cases without fatality), with the other third made up of criminal-justice and fatal costs. Total spending surrounding healthcare and substance abuse amounted to more than \$28 billion (\$21.4 billion to \$30.8 billion) from insurance coverage data and \$2.8 billion (\$2.6 billion to \$3.2 billion) from additional sources. Fatalities comprised over 25% of costs (\$21.5 billion, range of \$21.2 billion to \$21.8 billion).¹

The healthcare system bears approximately one-third of total costs estimated in this analysis. A significant amount of this cost burden is assumed by the federal government in the United States, with 14% funded by Medicare, Medicaid, and Champus/Veterans Affairs. Approximately 96% of costs (\$7.3 billion) related to criminal justice is related to activities directly funded by either local or state governments. When taken together, approximately 25% of the aggregate economic burden is funded by public sources. It is important to note the magnitude of the difference between financing the consequences of abuse/dependence (96% of expenditures) versus financing the treatment of the disease (4%). It should also be noted that the definition of opioid abuse/dependence used in this study was that defined by the 9th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-9) diagnosis codes, and no distinction was made between prescription opioids and heroin in the analysis.¹

In November 2017, The Council of Economic Advisers (CEA) of the Office of the President of the United States published their own analysis on the economic burden created by the opioid crisis. Despite noting previous data such as the Florence et al study, this analysis presented the concept that previous data showed only a partial account of the actual damage inflicted by opioid misuse/abuse. The premise put forth was that the opioid crisis has worsened over recent years, with heroin abuse playing a larger role, and previous fatality statistics underestimated the true number of opioid-related fatalities. This study quantified the costs for opioid-related overdose deaths based on economic valuations for fatality risk reduction, using the “value of a statistical life” (VSL) measure often used by federal agencies. However, it must be noted that VSL estimates can vary among agencies and may be prone to overstatement. A range of VSL estimates must be considered in fatality cost estimates.² The CEA analysis adopted an approach proposed by a study by Aldy and Viscusi for preferred estimates for VSL. This study was notable for citing that VSL may vary by age, and the CEA adopted this method to allow VSL to vary with age to control for the age distribution among opioid-related overdose deaths studied.^{2,3} For nonfatal costs, the CEA study used the Florence et al estimates to obtain a per-individual measure of opioid misuse costs for nonfatal cases and multiplied that per-individual cost by the number of persons with opioid use disorder in 2015.²

Results from the analysis estimated the total economic costs of the opioid epidemic at \$504 billion (\$239.9 billion to \$622.1 billion).

This \$504 billion estimate was reached by combining \$72.3 billion for nonfatal consequences (eg, healthcare costs for substance abuse therapy, criminal-justice costs, reduced productivity of 2.4 million nonfatal cases of opioid use disorder) with \$431.7 billion related to lives lost/fatality costs.^{2,4} The CEA noted that their cost estimate is significantly higher because of their accounting for lives lost based on standard federal methods in cost-benefit analyses for health-related intervention. In addition, the results of the study indicate that the overall opioid crisis itself has worsened substantially with overdose deaths doubling over the past decade. This analysis also considered both prescription and illicit (heroin) opioids, while previous studies tended to concentrate on prescription drugs. The overdose deaths were adjusted upward based on recent research that found significant underreporting of opioid-related overdose fatalities.^{2,5} This investigation compared reported opioid-involved mortality rates calculated directly from death certificates to corrected rates that attributed drug involvement when no drug was specified. Results showed that corrected opioid mortality rates were 24% greater than those reported.⁵

Using Step Care in Pain Management Instead of Opioids as First-Line Therapies

One point of argument in this country is the concept that clinicians overprescribe opioids, including as first-line therapy for pain management. It has been estimated that enough prescriptions for opioids were written to provide 1 of every 3 Americans with an opioid prescription in 2015, and nearly 92 million adults (38% of the US population) used a prescribed opioid during the same year according to a survey from the National Survey on Drug Use and Health. The survey also found that 11.5 million people (5% of the population) misused illicitly obtained prescription opioids. Data suggest there is now 4 times the level of opioid prescribing that existed 15 years before the survey.^{6,7}

One approach to provide appropriate pain management without using opioids as first-line therapy is the stepped-care model of pain management (SCM-PM) for those with chronic pain.⁸ Anderson et al implemented this model at a large, multisite, federally qualified health center (FQHC). This effort was guided by the Promoting Actions on Research Implementation in Health Services framework, and included⁹:

- Education on pain care
- New protocols for pain assessment and management
- Use of an opioid management dashboard
- Telemedicine consultations
- Enhanced onsite specialty resources

Twenty-five primary care physicians (PCPs) and their patients with chronic pain participated (3357 patient preintervention and 4385 patients postintervention). Data were obtained from the electronic medical records (EMRs) and direct chart reviews. The

involved PCPs received surveys to analyze their knowledge, attitudes, and confidence in pain management. Three steps were used as part of this SCM-PM effort (Figure).⁹

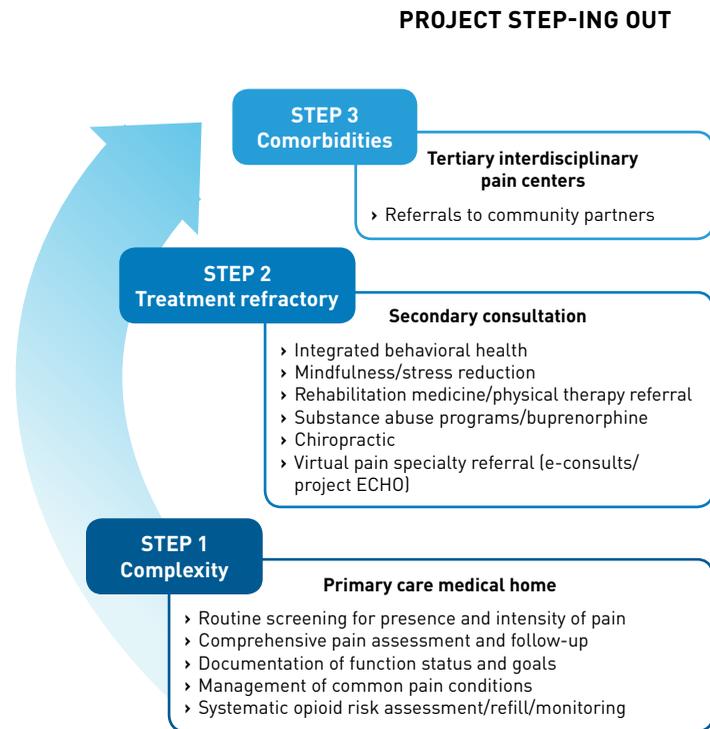
Interventions consisted of 6 educational and practice support elements⁹:

- Physician continuing medical education (CME)
- EMR pain templates for initial and follow-up visits
- Chronic pain and opioid prescribing policy requiring a signed opioid treatment agreement (OTA), 6-month urine drug tests (UDTs), and a standardized pain interference assessment every 3 months for those receiving opioids
- Opioid management dashboard including the requirements noted above (agreement, urine testing, pain interference assessment)
- Onsite specialty resources (eg, chiropractic care, pain-focused behavioral health interventions)
- Project Extension for Community Healthcare Outcomes (ECHO), providing videoconferences for PCPs to present complex pain cases to a multidisciplinary pain management team, with 1 PCP joining in weekly as the onsite pain “champion”

Results demonstrated improvements in multiple documentation elements (Table 1).⁹ Overall, PCPs’ pain knowledge scores increased 11% from baseline on average, and self-confidence in ability to manage pain was also enhanced. The use of OTAs increased by 27.3%, and the use of UDTs in this patient population increased by 22.6%. Notable improvements were recorded in documentation of pain, pain therapy, and follow-up. In addition, referrals to behavioral healthcare professionals for patients with chronic pain increased by 5.96%.⁹

Implementation of SCM-PM was also studied by Moore et al. Implementation occurred in the Veterans Health Administration (VHA) health-care system over 4 years, as well as a non-VHA FQHC over a 2-year period. This study involved a sampling of medical chart progress notes from both facilities from primary care prescribers

FIGURE. Modified Stepped Care Model for Pain Management at CHCI⁹



CHCI indicates Community Health Center, Inc; ECHO, Extension for Community Healthcare Outcomes. Reproduced with permission of Dove Medical Press via Copyright Clearance Center. Anderson DR et al. *Journal of Pain Research*. 2016;9:1021-1029.

TABLE 1. Pain Care Documentation Data Elements⁹

Chronic Pain Care Documentation Element	Baseline (March 2010–February 2011) N = 108 (%)	Evaluation (March 2013–February 2014) N = 213 (%)	P
Documentation of pain	69 (64)	174 (81)	<.001
Source or cause of pain	67 (62)	158 (74)	.025
Functional assessment	5 (5)	42 (19)	<.001
Review of diagnostic tests	6 (6)	37 (17)	<.003
Treatment plan	99 (92)	209 (98)	.006
Pain medication ordered	102 (94)	182 (85)	.017
Pain consult ordered	7 (7)	60 (28.2)	<.001
Patient education	16 (15)	47 (22)	.121
Diagnostic imaging ordered	25 (23)	59 (28)	.379
Assessment of treatment effectiveness	18 (17)	83 (39)	<.001

TABLE 2. Percentage of Patient Charts with Endorsed Pain Care Quality Outcomes in Department of Veterans Affairs Connecticut Healthcare System by Year^a

Measure	Kappa ^a	Project Step Year				P
		2008–2009 N = 174	2009–2010 N = 175	2010–2011 N = 160	2011–2012 N = 180	
Pain intensity rating	–	4.4	5.1	5.2	5.41	.04
Assessment	1.00	98.3	96.0	99.4	97.8	.05
Presence	1.00	93.7	96.0	98.8	97.8	.14
Function	0.63	38.5	42.3	23.8	48.9	<.001
Source	0.87	96.0	94.3	95.0	97.2	.54
Review	0.70	24.7	41.1	38.8	45.0	.001
Intervention	0.82	98.9	96.0	98.8	99.4	.15
Medication ordered	0.51	96.6	94.3	98.8	98.9	.06
Consultation ordered	0.73	16.1	10.3	15.0	6.7	.02
Specific pain plan	0.50	78.2	73.1	58.8	68.3	.001
Pain education	0.63	11.5	25.7	14.4	22.8	.003
Diagnostic ordered	0.87	8.6	9.1	4.4	5.0	.180
Reassessment	0.65	53.5	72.0	59.4	73.9	<.001

^aBased on 114 notes double coded for reliability.

TABLE 3. Percentage of Patient Charts with Endorsed Pain Care Quality Outcomes in Community Health Center, Inc, by Year^a

Measure	Year		P
	2011 N = 150	2012 N = 150	
Pain intensity rating	6.0	6.3	.40
Assessment	76.7	80.0	.61
Presence	65.3	71.3	.43
Function	6.7	10.7	.24
Source	64.0	66.7	.79
Review	4.7	8.7	.18
Intervention	100.0	100.0	>.99
Medication ordered	100.0	100.0	>.99
Consultation ordered	10.0	10.7	.87
Pain plan	96.0	95.3	.61
Pain education	16.0	18.7	.57
Diagnostic ordered	21.0	27.0	.22
Reassessment	20.0	28.7	.09

of opioid therapy to assess results following implementation of stepped care. The progress notes were coded for the presence or absence of pain care quality^a:

- Pain assessment
- Pain treatment plans
- Pain reassessment/outcomes
- Patient education

Within the systems studied, results showed significant improvements in pain assessment, pain treatment plans, and patient education with positive trends seen in all dimensions (**Table 2** and **Table 3**).⁸

Chronic Pain Management Guidelines/Recommendations

Clinical practice guidelines and recommendations should be followed when considering opioid use for chronic pain management. The American Society of Interventional Pain Physicians issued guideline recommendations for the use of opioids in the management of noncancer pain in 2017. Key areas/phases of focus are included in **Table 4**.¹⁰

Practitioners should also be aware of the current CDC guidelines for prescribing opioids for chronic pain, produced in 2016, which include 12 distinct recommendations grouped under 3 headings/categories, as seen in **Table 5**.¹¹ Overall, the CDC guidelines were designed to facilitate communication between clinicians and patients about the risks and benefits of opioids for chronic

pain, increase effectiveness and safety of pain therapy, and reduce risk of opioid use disorder, overdose, and fatalities. These guidelines will continue to be revisited and revised in the future to further improve patient outcomes in pain management.¹¹

The American College of Physicians (ACP) also addressed this issue in a 2017 guideline document for the management of lower back pain. Among their recommendations were the following¹²:

- **Recommendation 1:** Because most patients with acute or subacute lower back pain see improvement in their pain over time regardless of type of treatment, clinicians and patients should initially choose nonpharmacologic options for therapy. These may include superficial heat, massage, acupuncture, or spinal manipulation. If pharmacologic therapy is desired, nonsteroidal anti-inflammatory drugs (NSAIDs) or skeletal muscle relaxants should be chosen for therapy.
- **Recommendation 2:** For those with chronic lower back pain, initial therapy should also be based on nonpharmacologic options, including exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress reduction, tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback, low-level laser therapy, operant therapy, cognitive behavioral therapy, or spinal manipulation.
- **Recommendation 3:** For those with lower back pain not responding to nonpharmacologic therapy, first-line treatment with NSAIDs should be considered, with tramadol or duloxetine as second-line options. Opioids should only be considered in patients who have failed treatment with the recommended first- and second-line options, and only if the benefits of opioid use outweigh the potential risks for each individual patient.

According to the ACP, opioids should be considered the last treatment option for patients with chronic lower back pain who have not responded to other recommended therapy

TABLE 4. ASIPP Guidelines Key Areas of Focus¹⁰

Initial steps of opioid therapy	<ul style="list-style-type: none"> • Comprehensive patient assessment and opioid abuse screening • Establishment of treatment goals and medical necessity for opioid use, including patient risk stratification • Use of PDMPs, OTAs, and UDTs as part of management
Assessment of effectiveness of long-term opioid therapy	<ul style="list-style-type: none"> • Low-dose, SA drugs for initial therapy with appropriate monitoring • Avoidance of LA opioids for initial treatment, and recommendations to use methadone only after failure of other opioid therapy • Similar effectiveness of LA and SA opioid but increased adverse consequence for LA formulations • Consideration of LA or high-dose opioids only in special circumstances with severe intractable pain
Monitoring for adherence and adverse effects	<ul style="list-style-type: none"> • Monitoring for adherence, abuse, and noncompliance using UDTs and PDMPs • Monitoring for adverse effects and managing these appropriately, including opioid discontinuation where indicated
Final phase	<ul style="list-style-type: none"> • Monitoring with continued medical necessity • Discontinuation of opioid therapy for lack of response, adverse consequences, and abuse with rehabilitation

ASIPP indicates American Society of Interventional Pain Physicians; LA, long-acting; OTA, opioid treatment agreement; PDMP, prescription drug monitoring program; SA, short-acting; UDT, urine drug test.

TABLE 5. CDC Recommendations for Prescribing Opioids¹¹

Determining when to initiate or continue opioids for chronic pain	<ul style="list-style-type: none"> • Opioids are not first-line therapy; nonpharmacologic treatments and nonopioid drugs are preferred • Establish goals for pain and function; clinician/patient collaboration • Discuss risks and benefits of opioid therapy
Opioid selection, dosage, duration, follow-up, and discontinuation	<ul style="list-style-type: none"> • Use immediate-release opioids initially instead of ER/LA opioids • Use the lowest effective dose in terms of MMEs, with reassessment before increasing dosage to ≥50 MME/day and avoidance of titration to ≥90 MME/day (or careful justification for that high a dose) • Prescribe short durations of therapy for acute pain • Evaluate risks/harms vs benefits frequently, initially at 1 to 4 weeks of opioid initiation and every 3 months or less thereafter
Assessing risk and addressing harms	<ul style="list-style-type: none"> • Use strategies to mitigate risk, including potentially offering naloxone when risk factors are present • Review PDMP data to assess potential risky opioid doses or drug combinations • Utilize a UDT, at least annually, to assess for prescribed (and nonprescribed) drugs • Avoid concurrent opioid and benzodiazepine prescribing • Offer treatment for opioid use disorder (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapy)

ER indicates extended release; LA, long-acting; MME, morphine mg equivalent; PDMP, prescription drug monitoring program; UDT, urine drug test.

TABLE 6. Advantages and Limitations of Current ADF Technologies¹⁴

ADF Technology	Advantages	Limitations
Physical and chemical Barriers	<ul style="list-style-type: none"> • May prevent chewing, crushing, grating, or grinding • May prevent accidental crushing or chewing in compliant patients • May resist extraction by solvents • No AEs in compliant patients 	<ul style="list-style-type: none"> • Does not deter abuse of intact tablets
Agonist/antagonist combinations	<ul style="list-style-type: none"> • Antagonist may be formulated to be clinically active only when manipulated • May curb euphoria when formulation is compromised 	<ul style="list-style-type: none"> • Inadvertent chewing or crushing may reduce analgesic effects and/or precipitate AEs or opioid withdrawal symptoms
Aversion	<ul style="list-style-type: none"> • Aversive agents may be combined with the opioid to create unpleasant AEs when manipulated or taken at higher doses • May prevent abuse by chewing or crushing • May limit abuse of intact tablets 	<ul style="list-style-type: none"> • Potential for unpleasant AEs in compliant patients who take product as intended • AEs with intact tablets may prevent legitimate dose increases • AEs may not be sufficient to deter a motivated abuser
Delivery system	<ul style="list-style-type: none"> • The method of drug delivery can offer resistance to abuse (eg, depot formulations or subcutaneous implants) 	<ul style="list-style-type: none"> • It may still be possible to extract the opioid from the formulation
Prodrug	<ul style="list-style-type: none"> • A prodrug that lacks opioid activity until transformed in the gastrointestinal tract may be unattractive for intravenous or intranasal routes of abuse 	
Combination	<ul style="list-style-type: none"> • A combination of 2 or more of the above approaches 	

ADF indicates abuse-deterrent formulation; AEs, adverse effects.

options because of the significant potential harm they can cause. Studies that have addressed opioids for use in chronic lower back pain have not addressed the risk for addiction, abuse, and overdose. Data from observational studies have demonstrated a dose-dependent relationship between the use of opioids and potentially serious AEs.^{12,13} Clinicians should select therapies for chronic lower back pain that deliver the fewest harms and also lower costs overall because there are no distinct comparative advantages for most treatments.¹²

The Value and Limits of Abuse-Deterrent Opioid Formulations in Therapy

The development of abuse-deterrent formulations (ADFs) has been an important advance in the armamentarium to fight opioid misuse and abuse and to reduce diversion of these therapies. ADFs are designed to prevent extraction of the active drug in formulations, prevent administration through alternative routes and/or make abuse of a manipulated agent less appealing. ADFs can still lead to abuse via the intended route of administration by increasing dosage or frequency of administration. The science of ADFs and regulatory landscape surrounding them continues to evolve, as do their usage in clinical practice.¹⁴ ADF technologies present both advantages and limitations for use in clinical practice, as seen in **Table 6**.¹⁴

Although considered effective alternatives, ADFs have not proven to be a panacea for opioid abuse, misuse, and diversion. A study by Cassidy et al assessed patterns of abuse of opioids and other drugs after the introduction of the reformulation of oxycodone

hydrochloride controlled-release tablets (ADF). This study used a sentinel sample of 232,874 adults assessed for substance abuse treatment at 437 facilities to evaluate for quarterly prevalence of past 30-day abuse and changes in abuse pre- and post-introduction of the ADF agent. Results demonstrated that increased abuse prevalence occurred for all prescribed opioid classes (pre-post relative risk = 1.08) and for extended-release (ER) opioids (relative risk = 1.11). In fact, there was a nearly 3-fold increase in the abuse of ER oxycodone and a 2-fold increase for buprenorphine in the time period after the introduction of ADFs, and the increases were prominent among patients who reported abuse by preferential administration routes, including oral, nasal (snorting), and injectable administration. The investigators concluded that additional follow-up studies will be needed to monitor changing opioid abuse patterns and their impact on public health as newer ADFs and other formulations are developed and introduced as therapy options.¹⁵ Other studies have also identified trends of patient switching from ADFs to more easily abused opioids, further emphasizing the need to monitor abuse patterns, as noted in the Cassidy analysis.¹⁶⁻¹⁸

The economics and potential cost increases or savings with ADFs continue to be elucidated. For example, data from Kirson et al have suggested that the ADF reformulation of oxycodone hydrochloride is associated with an estimated \$340 million in annual medical cost savings along with \$605 million in indirect cost savings, providing a total annual societal cost savings estimated at \$1.0 billion in the United States. Such savings associated with reduction in opioid abuse could

continue to grow with the development and introduction of more ADFs.^{14,19} However, these potential cost benefits must be considered in conjunction with the often-higher cost of these opioid formulations. It has been estimated that the average additional costs for ADF opioids would range from approximately \$600 to \$2800 per month, depending on the individual drug.^{20,21} And in contrast to the Kirson study, a study by Keast et al found that greater Medicaid expenditures were discovered in 2013 and 2014 for patients who were prescribed ADFs versus standard opioid agents. ADF costs were estimated at \$24,979 versus \$15,043 (per patient) for the traditional opioids.^{21,22} The economic impact of ADFs can be better elucidated by considering overall healthcare costs associated with opioid abuse along with the cost impact on patients shifting to other opioid formulations. Careful selection of patients in need of ADF products is important in maximizing the cost-benefit ratio of ADF products.²¹

Prior Authorization and Opioid Management

Prior authorization (PA) remains an important aspect of prescribing and medication management. PA is administered to ensure that benefits for prescribed drugs are administered as designed. With PA, patients receive the most appropriate agents while waste, error, and unnecessary drug usage and cost are diminished.²³ The PA process requires the prescribing clinician to receive pre-approval for prescribing a certain pharmaceutical for that agent to qualify for coverage under terms laid out in the pharmacy benefit plan.^{23,24} If a drug requires a PA, it will not be approved for payment until conditions for approval and use are met and the PA is actually entered into the ordering system. The procedures for PA and requirements for coverage are based on both the actual clinical need and therapeutic justification for use of that drug. The PA process allows a prescriber to justify the therapeutic rationale and need for a specific drug for an individual patient.^{23,25}

PA is considered a tool to both promote appropriate drug use and prevent misuse/abuse. In some cases, including prescribing of opioid drugs, PA may be used to limit coverage in certain situations to patients where safety and appropriate use has been documented, especially if there is not enough clinical evidence to support the use of a medication for an off-label indication (eg, an opioid approved for breakthrough cancer pain but not for chronic low back pain). Step therapy is also an approach used as part of PA, requiring the use of clinically recognized first-line drugs before approval of a more complex and costly agent where safety, effectiveness, and value have not been established for a specific medical condition.²³

PA has been used to potentially lower the rates of opioid misuse and abuse. A study by Cochran et al compared rates of opioid abuse and overdose in Pennsylvania Medicaid enrollees in plans that varied in their use of PA, namely requiring PA for 17 to 74 opioids (high PA); requiring a PA for 1 opioid (low PA); or those requiring no PA policies for opioid drugs. Assessments were made between the

presence of PA policies and opioid abuse and overdose, measured in Medicaid claims data. Overall, there were 297,384 enrollees included, comprising 382,828 opioid treatment episodes. Enrollees in high and low PA plans were found to have lower rates of abuse compared with plans that had no PA policies. Individuals in high PA plans were found to be 11% less likely to develop opioid abuse than patients in plans with no PA, and enrollment in a low PA plan was associated with a 7% lower rate of abuse development in comparison enrollment in a no-PA plan. Adjusted rates of abuse were 2.49% for high PA, 2.58% for low PA, and 2.76% for no PA per average person-days. Those in low-PA plans had lower adjusted overdose rates than those in no-PA plans, and those patients in high-PA plans were also less likely to overdose versus those enrolled in no-PA plans, although this association did not reach statistical significance (adjusted rate ratio of 0.21, 0.17, and 0.23 for high, low, and no PA, respectively). Overall, the investigators concluded that Medicaid plans using PA policies appeared to have lower rates of opioid abuse and overdose following opioid therapy initiation.²⁶

However, PA also has created troublesome and disruptive barriers affecting both prescribers and patients. A previous survey of 2400 physicians by the American Medical Association (AMA) found that two-thirds of physicians reported waiting times of several days to receive a PA for prescribed drugs, with 10% of those reporting waits of more than a week.²⁷ More recent data from 2017 demonstrated that 33% of physicians waited 1 to 2 business days for PA, with 20% reporting delays of 3 to 5 business days.²⁸ In addition, 75% of physicians recently surveyed described PA burdens as high or extremely high and nearly one-third reported having staff in place who exclusively work on PA. Nearly 90% reported that PA sometimes, often, or always delays access to healthcare.²⁹

These delays created uncompensated work for clinicians that translated into increased overhead costs for clinical practices. Estimated costs of prior authorization included²⁷:

- 1 physician hour per week²⁷
- 13.1 nursing hours per week²⁷
- 6.3 clerical hours per week^{27,30}
- \$2161 to \$3430 annually per full-time-equivalent (FTE) physician^{27,31}
- \$89,975 in interactions with insurers annually per physician^{27,32}

Because of this burden on physicians and their fellow clinicians and staff, the AMA and 16 other partner medical society and specialty organizations have proposed programs and processes centered on clinical validity, continuity of care, transparency and fairness, timely access and administrative efficiency, and alternatives and exemptions for improvement of the PA process. Based on outlined principles, these recommendations focus on these noted areas to streamline requirements, lengthy assessments, and inconsistent rules that negatively impact current PA programs.^{28,33}

Managed Care and Pharmacy Opportunities for Preventing Opioid Abuse/Misuse

Managed care providers and professionals must strive to achieve concomitant goals of ensuring that patients with legitimate pain have access to opioid pain medications when truly necessary while minimizing opioid misuse. Internal strategies to accomplish this may include pharmacy and prescriber controls that limit reimbursement to ensure that higher risk opioids are not provided unless their benefits exceed their inherent risks and that appropriate drug use monitoring is employed. Using opioid formulations that minimize abuse/diversion is another valuable tool, as is surveillance of claims data for overuse of opioid agents. Claims data can also identify individuals at greater risk for drug abuse, including those with mental health disorders and substance use issues.³⁴ Clinicians may adopt “universal precautions” in working with these patients, including screening and risk stratification for opioid abuse/misuse, patient education and counseling that encourages patient involvement in decision making and therapy, use of UDTs, pill counts, or other measures to assess for problems, and careful documentation of the entire pain management process.^{34,35} The use of Screening, Brief Intervention, and Referral to Treatment may also be implemented, using brief interventions or treatment for low to moderate risk cases and referral to a pain specialist for high-risk patients. In addition, case management offering support to clinicians, and especially patient education and increased communication between clinicians/providers and patients, can all enhance the pain-management process and reduce risks and events associated with opioid abuse/misuse.^{34,36}

Pharmacists are also valuable stakeholders in ensuring safe use of opioid drugs.³⁷ Pharmacists can incorporate risk-stratified opioid screening in everyday practice by asking open-ended questions and actively listening for potential clues that suggest opioid misuse. Data within the Controlled Substance Reporting System also permits pharmacists to identify patients at increased risk for opioid overdose, including those taking high-dose agents, filling multiple prescriptions for different drugs, or patients obtaining opioids from multiple prescribers or several different pharmacies.^{37,38} Pharmacists must also be vigilant about instructing patients on safe opioid storage and disposal. A study by Kennedy-Hendricks et al reported that 48.7% of adults receiving prescriptions for opioids did not recall receiving instructions on safe storage of these agents, and 45.3% did not receive explanations on safe disposal.^{37,39} Overall, pharmacists must serve as a critical line of defense against opioid misuse and abuse by more active engagement in preventing and helping to treat opioid use disorders.³⁷

Outside resources also benefit patients with chronic pain taking opioid medications. Patients with chronic pain frequently require a management approach that allows them to talk freely about their pain and gain support for how they are feeling while also being

aided to adapt to an active and meaningful life alongside their pain. Psychotherapy or other consultation with a behavioral health specialist can enhance this process.⁴⁰ It is also important to recognize when a patient may be developing a substance use disorder and may need referral to an addiction specialist for treatment and management, including⁴¹:

- When a brief assessment or intervention is not adequate for optimal management
- When opioid or illicit drug abuse is suspected
- When a patient has a complex medical history or a previous history of substance abuse and requires more intensive treatment than can be provided in the current clinical setting
- When a patient is noncompliant with treatment protocols or clinical practice policies surrounding opioid therapy
- When a patient is showing dependence on high-dose long-acting or short-acting opioids, or is requesting a transfer from high-dose methadone maintenance
- When a patient requests a referral for treatment of substance abuse

Conclusions

Optimal treatment of chronic pain remains a dilemma in the United States, and the detrimental impact of opioid misuse has inflicted serious clinical and economic complications on patient management and public health overall. Healthcare professionals must be better prepared to appropriately evaluate opioid treatment options and better delineate their safe administration, efficacy, and safety, including guidelines for management, the best use of ADFs, and how PA and specialty referral may benefit overall patient management. It is most important to concentrate on individualized management based on clinician and patient collaboration surrounding therapy to select the best treatment options that offer clinical benefit and patient safety and reduce the potential for opioid misuse and addiction and their associated clinical and economic burden. ■

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