Daiichi Sankyo, Inc.

Pain Trends Report

SECOND EDITION | 2018

Daiichi-Sankyo

Foreword

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In the 2 years since Daiichi Sankyo, Inc., published the first edition of the *Pain Trends Report*, the pain category has undergone an immense transformation. The opioid abuse epidemic has captured the national spotlight and riveted public attention. Stakeholders in healthcare and government have elicited action to address issues associated with opioid abuse and misuse, which has led to increased scrutiny of pain management. The second edition of the report keeps pace with these developments as it shares current insights into pain management and how the landscape continues to evolve.

Amid this often polarizing environment, pain remains a category with significant unmet needs. Millions of people suffer from pain, often struggling to find the relief they need. At the same time, more than 1000 people are treated every single day in emergency departments across the United States for not using opioids as directed.[1] As concern about the abuse of prescription pain medication mounts, health plans and providers must balance the need to provide pain relief with the need to limit risks associated with certain pain treatments.

Drawn from the insights of those deeply immersed in pain management, the second edition of the report uncovers key issues surrounding pain management and the various ways stakeholders are attempting to address these issues. This resource offers both a broad overview of the pain landscape and a closer look at the trends, topics, needs, and challenges unique to the pain category. For example, more than half of payers and clinicians and nearly three-quarters of employers are tracking legislation and marketplace changes related to pain management. Payers are trying to find ways to minimize the potential for opioid abuse—about two-thirds use quantity limits—while clinicians are sharply reducing the average duration of initial opioid prescriptions.

Daiichi Sankyo, Inc., is committed to being a responsible, collaborative partner in the appropriate management of pain. The *Pain Trends Report* has been a valuable resource for communicating important information about pain management, and we are proud to continue that tradition. Whatever your discipline or level of involvement in pain management, I encourage you to review the findings in the report. I am confident that the *Pain Trends Report* will enhance our collective understanding of the complex issues involved in pain management.

We would like to acknowledge the esteemed members of our Editorial Board for their invaluable contributions and feedback, which were instrumental in guiding the development of the report.

We hope you find the second edition of the report to be engaging and informative. Thank you for your continued interest in this initiative.

Sincerely,

Ken Keller

Reference: 1. Prescription opioid overdose data. Centers for Disease Control and Prevention website. https://www.cdc.gov/drugoverdose/data/overdose.html. Updated August 1, 2017. Accessed May 18, 2018.

Editorial Board

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The *Pain Trends Report* was developed by Daiichi Sankyo, Inc., with input from the members of the Editorial Board. Daiichi Sankyo, Inc., compensated the members of the Editorial Board for their contribution.

Table of Contents

Daiichi-Sankyo

Introduction

Though a universal concept, pain as a clinical category is far from straightforward. Pain is characterized by unpleasant physical sensations and psychological components that manifest differently from patient to patient,[1] requiring healthcare professionals and key decision makers to be highly cautious with their diagnoses, treatment, and management decisions. With a heightened focus on the potential risks that can accompany certain pain treatments, the pain management landscape is continually evolving.

The second edition of the Daiichi Sankyo *Pain Trends Report* continues to share diverse perspectives on the pain category and its management. Drawn from the insights of those immersed in the management and treatment of pain, including payers, clinicians, and employers, this edition discusses key topics relevant to the current pain landscape and its many complexities. Subjects of interest include unmet needs, management challenges and financial strategies, opioid prescribing and addressing prescription drug abuse, and treating neuropathic pain.

Economic impact

Pain places a significant financial burden on both government and commercial payers and has continued to be both a high-spend and high-volume category in recent years. According to the past 2 Express Scripts® Drug Trend Reports, pain/inflammation was among the therapy categories with the highest PMPY spend for commercial plans, ranking fifth in 2016 and sixth in 2017. Among traditional therapy categories, it was second highest both years.[2,3,a] In 2016, there was an average of more than 1 prescription PMPY, and over 95% were for generic medications, making volume a driver of high category costs.[2]

In the United States, the annual cost of pain has been estimated at $560 to $635 billion, an amount equal to approximately $2000 for every individual living in the United States (2010 dollars).[4,b] Additionally, pain severity is directly related to healthcare expenditures (see Figure 1).

Figure 1. Pain severity and healthcare expenditures[4]

Clinical features

Pain can be categorized in a variety of ways: it can be mild to severe, acute or chronic, localized to one area or diffuse throughout an entire region of the body. Another important clinical distinction is the difference between nociceptive and neuropathic pain. Nociceptive pain results from activity in neural pathways, whereas neuropathic pain is initiated by dysfunction or lesions in the nervous system.[1] Treatment approaches and patient outcomes are dependent on both pain type and severity.

Nociceptive pain: Acute nociceptive pain can arise from time-limited conditions, such as injury, surgical or dental procedures, or illness. Additionally, 42% of visits to the emergency department are prompted by painful conditions.[5] If inadequately treated, acute pain can lead to the development of chronic pain that can persist for months or even years. It is estimated that chronic pain affects at least 116 million adults in the United States.[4] Chronic pain can also emerge alongside other medical conditions, such as cancer or rheumatoid arthritis. Common medications used to treat nociceptive pain include acetaminophen, NSAIDs, and opioid analgesics.[6]

Neuropathic pain: A recent survey estimated that the overall prevalence of neuropathic pain in the United States is 10%.[7] Though neuropathic pain is most often chronic in nature, it may also develop acutely.[1] Neuropathic pain can be very difficult to diagnose and treat, as it can have an unclear cause, developing either on its own or as a result of other

[a]Excludes inflammatory conditions.

[b]For noninstitutionalized adults.

Abbreviations: NSAIDs, nonsteroidal anti-inflammatory drugs; PMPY, per member per year.

Introduction

medical conditions.[1] Three common conditions that are often associated with neuropathic pain are diabetic peripheral neuropathy, postherpetic neuralgia, and cancer.[1] In a 2017 survey, the most commonly reported medications used by patients with symptoms of neuropathic pain included NSAIDs, opioid analgesics, and antiepileptics.[7]

Treatment approach: efficacy, safety, and associated risks

For optimal efficacy and patient safety, current clinical guidelines and professional pain societies recommend that pain be treated with a multimodal approach that includes both pharmacologic and nonpharmacologic treatments.[8-10] Setting appropriate patient expectations for pain relief has become another important aspect of pain management, particularly for patients suffering from chronic pain. Professional societies, such as the AMA, have fought against the policy of pain as the "fifth vital sign," arguing that this approach sets unrealistic patient expectations that pain can be eliminated.[11] Additionally, these groups have spoken out against tying pain-related patient satisfaction measures to reimbursement, arguing that it has led to irresponsible prescribing of opioids. Amid significant pressure, CMS changed its Hospital Value-Based Purchasing formula, removing the patient satisfaction metric in the pain management component of the HCAHPS survey. Starting January 2018, the pain survey questions now focus on patient communication about pain. Scoring will be publicly reported starting in 2019, with changes to reimbursement beginning in 2020.[12]

As part of discussions about safe prescribing and best practices, pain management has received heightened attention. Though certain medications are highly effective in controlling pain, there is also a high potential for abuse. Indeed, the problems of opioid abuse and addiction have reached epidemic proportions. The balance of treating legitimate pain while limiting abuse and addiction has become increasingly important to many healthcare professionals and health systems.

Opioid abuse: a national crisis

Figure 2. Opioid abuse by the numbers

53% of opioid misusers/abusers **obtain prescription pain relievers from friends or relatives.**[15]

As many as **1 in 4 people** who receive prescription opioids for long-term noncancer pain in a primary care setting **struggle with addiction.**[13]

In response to the large number of overdoses and fatalities, many federal and state agencies have implemented new strategies in an attempt to limit opioid abuse and provide treatment for those suffering from addiction. On October 26, 2017, the White House declared the opioid abuse epidemic to be a public health emergency.[16] As part of the declaration, resources were allocated to permit the hiring of specialists to combat the issue and expand the use of telemedicine services to treat people in rural areas who often lack immediate access to care.[16] Additionally, a report published in November 2017 by the Council of Economic Advisers cited the total cost of the opioid epidemic as $504 billion in 2015.[17]

[a]Includes overdoses from prescription opioids and illicit opioids (eg, heroin).

Abbreviations: CMS, Centers for Medicare and Medicaid Services; HCAHPS, Hospital Consumer Assessment of Healthcare Providers and Systems.

Introduction

CDC and HHS: The CDC Prevention for States program provides funding for states to implement strategies to prevent prescription drug overdoses, including ways to maximize the use of prescription drug monitoring programs (PDMPs) and improve prescribing interventions for insurers and health systems.[18] HHS has published a 5-point strategy to combat the crisis, which includes plans for improved addiction prevention, treatment, and recovery systems.[14] Alongside federal efforts, individual states have also implemented their own stlike i rategies. One of the most common strategies is the expanded or mandatory use of PDMPs for clinicians and pharmacists.

FDA: As part of its response to the opioid abuse epidemic, the FDA published guidance for manufacturers on the development and evaluation of ADFs in 2015.[19] Though ADFs are not abuse proof, they are expected to play an important role in addressing problems associated with abuse and misuse, such as drug manipulation. Already, there are several branded ADFs that have followed the guidance and received FDA-approved abuse-deterrence claims. However, there is concern about the cost implications of introducing branded ADFs into a highly generic market. In an attempt to encourage further ADF development but minimize costs, the FDA issued another guidance in November 2017 that provides information regarding the evaluation of generic oral ADFs.[20]

MME restrictions: Another concern related to the opioid abuse epidemic is the prescribing of high daily dosages of opioids. Additional guidance on best practices for prescribing has been disseminated in order to help clinicians safely prescribe opioids and appropriately treat pain. Many of these suggested prescribing practices encourage daily dosage limits. For example, the CDC Guideline for Prescribing Opioids for Chronic Pain recommends avoiding dosages of ≥90 MME/day or carefully justifying a decision to titrate to a dosage higher than the guideline's suggested limit.[21] Based on these guidelines, CMS has also adjusted its opioid overutilization criteria, which help CMS identify registered Medicare Part D providers who may be overprescribing opioids. According to the new criteria (effective 2018), a drug utilization review will flag a clinician as a potential overprescriber if he or she prescribes opioid doses that exceed the CDC guideline's limit of 90 MME/day.[22] Some states have signed laws with opioid prescribing restrictions that reflect these types of dosage limits. Payers are also implementing similar quantity limits within their plans in light of these changes.

Everyone, including clinicians, pharmacists, insurers, caregivers, government entities, and pharmaceutical companies, has a distinct role in helping address the problem of prescription drug abuse and ensuring patient safety.

The second edition of the *Pain Trends Report*

The pages that follow present proprietary, primary survey data that demonstrate key stakeholder opinions on relevant topics and trends in pain management. This information serves to expand and enhance readers' knowledge of the pain landscape by uncovering its challenges and intricacies through the lenses of different individuals directly involved in pain management. Understanding these diverse perspectives will help guide utilization review managers, employers, plan administrators, and other decision makers as they develop pain management strategies that ensure patients receive the safest, most effective care for their pain.

Key terms[23-25]

Abuse: The use of illegal drugs or inappropriate use of legal drugs, including repeated use of drugs to produce pleasure, alleviate stress, and/or alter or avoid reality.

Addiction: A chronic, relapsing brain disease that is characterized by compulsive drug seeking and use despite harmful consequences.

Dependence: A condition that develops after repeated exposure to certain drugs, caused by neurons adapting to the repeated drug exposure. Without continued exposure to the drug, the neurons cannot function normally.

Misuse: Taking a legal prescription medication in a manner other than prescribed, even if for a medical complaint.

Abbreviations: ADFs, abuse-deterrent formulations; MME, morphine milligram equivalent.

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Methodology

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SURVEY DESIGN

Surveys were developed to gather information from 3 core stakeholder groups in pain management. These 3 stakeholder groups were selected based on their collective ability to represent different points of view about the pain category and its impact on the US healthcare system. Payers in the survey were representative of both managed care organizations (MCOs) and integrated delivery networks (IDNs).

Detailed screening criteria and participant quotas were created for each stakeholder group. Stakeholder-specific criteria helped prequalify each participant, assuring experience and responsibilities relevant to pain management in his or her organization or practice.

Payers were prequalified to have influence on organizational policies regarding pain management and familiarity with the pain category. No pharmacy benefit managers were included in the survey in order to avoid any double counting of lives.

Clinicians were prequalified to be familiar with oral prescription pain medication and the treatment of adults with at least 1 type of pain: acute nociceptive pain, chronic nociceptive pain, or neuropathic pain. Clinicians included physicians, nurse practitioners, and physician assistants.

Employers were prequalified to have a self-insured pharmacy benefit and to be involved, experienced, and familiar with that pharmacy benefit.

Survey questions investigated a variety of topics, including pain category management, the impact and cost of pain, unmet needs, and prescription opioid abuse. Questions were customized for each survey audience.

SURVEY EXECUTION

Quantitative web-based surveys were administered to payers, clinicians, and employers in September and October of 2017. Individual telephone interviews were conducted with a subset of respondents to gain additional insights and gather quotes to support survey findings. Each quote included in the report represents the views of one individual and is not representative of the views of the broader survey population or Daiichi Sankyo, Inc. The survey results were obtained by Managed Markets Communications, a Syneos Health company, in order to ensure confidentiality.

Methodology

PROFILE OF SURVEY RESPONDENTS

A total of 234 stakeholders responded to the survey. Figure 1 provides a sample breakdown of each stakeholder group. More detailed demographic information can be found at the beginning of each stakeholder chapter.

Figure 1. Surveyed stakeholders

Payers
(N = 40)

- **MCO respondents**
  (N = 30)
  – 194,520,000 covered lives
- **IDN respondents**
  (N = 10)

Clinicians
(N = 169)

- **Physicians**
  (N = 119)
- **Nurse practitioners**
  (N = 25)
- **Physician assistants**
  (N = 25)

Employers
(N = 25)

- **Company size**
  (number of employees)
  – 8 small (101-500)
  – 9 medium (501-5000)
  – 8 large (>5000)

DATA ANALYSES AND REPORTING

All data were blinded, and no information about specific pain products was collected or reported. Once the data analyses were completed, Daiichi Sankyo, Inc., received aggregated data that did not include any identifying information about the participants.

Expert review

Daiichi Sankyo, Inc., convened an Editorial Board of 5 key opinion leaders representing payers and clinicians to ensure that the report is both accurate and relevant to readers. The Editorial Board reviewed the surveys and helped with both data interpretation and report development. Daiichi Sankyo, Inc., compensated the members of the Editorial Board for their contributions.

Executive Summary

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Payers N = 40

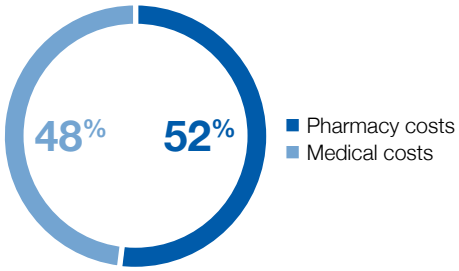
Clinicians N = 169

Employers N = 25

234 total stakeholders

THE COST OF PAIN

Payer breakdown of pain costs



Employer perspective on pain costs

64% of employers rated pain as the **top cost driver** related to impaired employee productivity and absenteeism.

52% of employers rated **increasing prescription costs** as the greatest challenge in pain management.

GREATEST UNMET NEEDS IN PAIN MANAGEMENT

More effective analgesia

This was the most commonly identified unmet need for neuropathic pain by >60% of payers and clinicians.

Abbreviation: ADFs, abuse-deterrent formulations.

Executive Summary

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ADDRESSING OPIOID ABUSE

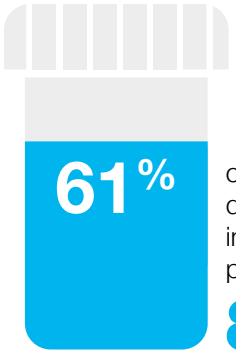
Top payer efforts to minimize opioid abuse

1. Quantity limits
2. Utilization management
3. Monitor prescribing behavior

Clinicians are prescribing...

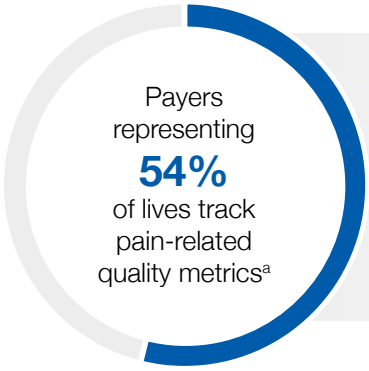
More NSAIDs, acetaminophen, and ADFs

Fewer opioids and **lower** daily dosages of opioids



of clinicians have **shortened** the duration of initial opioid prescriptions in the past 2 years. On average, prescriptions are shorter by **8.5** days.

QUALITY METRICS



Impact:

- **Decreased** number of patients on high doses of opioids (72%)
- **Improved** patient safety (56%)
- **Reduced** overall healthcare costs (53%)

TRACKING LEGISLATION AND MARKETPLACE CHANGES

Payers: **52%** of lives[a]

Clinicians: **39%**

Employers: **72%**

[a]Data by lives are representative of managed care organizations only.

Abbreviation: NSAIDs, nonsteroidal anti-inflammatory drugs.

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INTRODUCTION

The pain category places a significant burden on US payers. This chapter explores the payer perspective on a variety of topics, including category management, costs, unmet needs, and other key issues in pain management. Payer respondents included pharmacy and medical directors from both managed care organizations (MCOs) and integrated delivery networks (IDNs).

PAYER DEMOGRAPHICS

30 MCOs

MCO respondents

N = 30

194,520,000 covered lives*

10 IDNs

IDN respondents

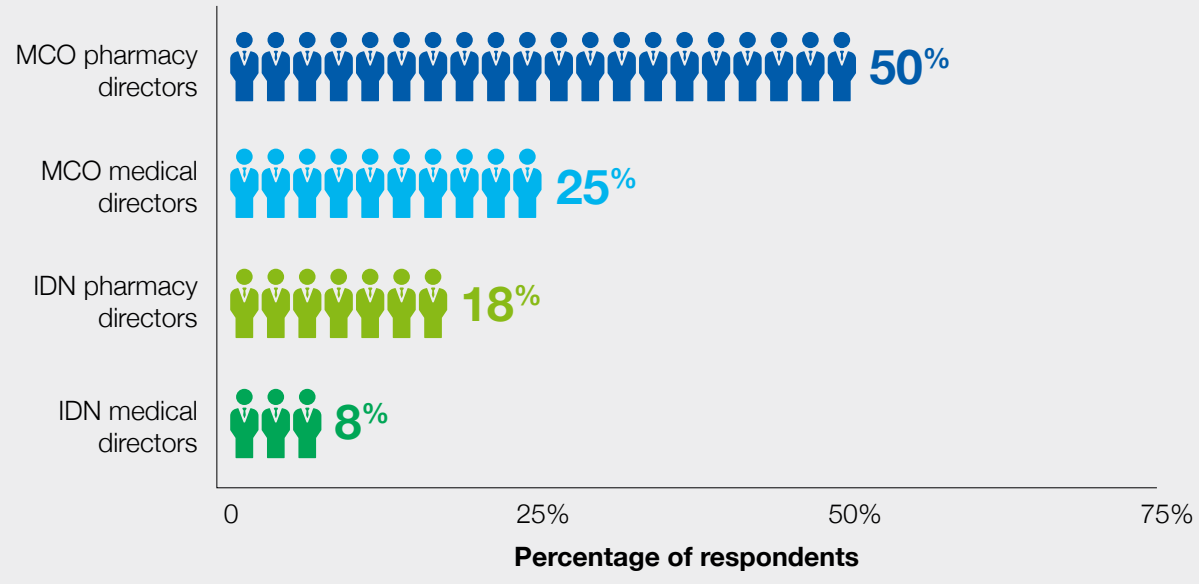
N = 10

Data throughout this chapter are displayed for the full sample (N = 40 payers; N = 194,520,000 lives) with the exception of data that reflect responses from only a subset of the full sample, in which case the n value is displayed.

Additionally, data for covered lives are only provided for payers from MCOs. For data results representing covered lives, the respondents' total number of covered lives was used to weigh the results. Data results for IDNs reflect the full sample (N = 10).

Throughout this chapter, totals may not equal 100% due to rounding.

Respondent roles
N = 40 payers



*What is the total number of lives covered by your organization? (No pharmacy benefit managers were included in the survey in order to avoid any double counting of lives.)

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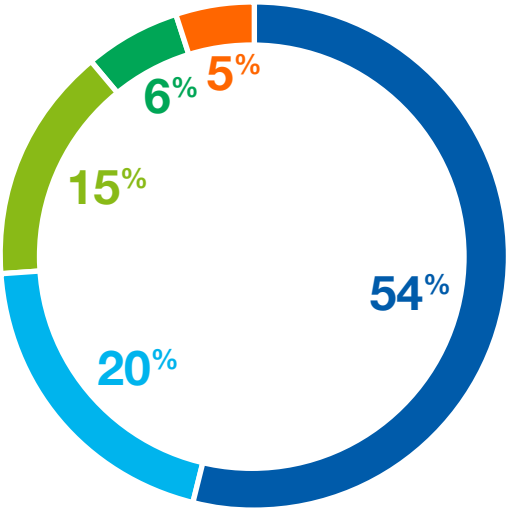
PAYER DEMOGRAPHICS (cont'd)

MCO characteristics

Average books of business*



IDN characteristics

Average network size†

61
outpatient facilities

18
hospitals

7
retail/community pharmacies

$44.7M
in annual revenue

2371
employed physicians

2.23M
annual patient visits

*How does your organization's total membership break down by each of the following books of business?

†How large is your organization?

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UNMET NEEDS

Overall, payers agreed that there are remaining unmet needs in pain management, particularly those that relate to addressing prescription drug abuse and providing adequate pain relief.

When asked about acute nociceptive, chronic nociceptive, and neuropathic pain, payers noted different unmet needs. For acute and chronic nociceptive pain, the most commonly reported unmet needs were related to opioid abuse, whereas for neuropathic pain, the majority of payers agreed that the need for products that provide effective analgesia was a top unmet need.

Greatest unmet needs in pain management*

58% Additional ADFs

50% New class of pharmaceutical pain medication

45% Reduced side effects

35% More effective analgesia

33% Greater access to existing ADFs

Acute nociceptive pain

56% of payers reported high unmet needs.[a†]

Top identified needs

n = 22[a‡]

1. Lower abuse potential (41%)
2. More effective analgesia (27%)
3. New class of pain medication (14%)
4. More prescriber education (9%), reduced side effects (9%)

Chronic nociceptive pain

73% of payers reported high unmet needs.[a†]

Top identified needs

n = 28[a‡]

1. Lower abuse potential (43%)
2. Reduced side effects (32%)
3. New class of pain medication (25%)
4. More effective analgesia (21%)

Neuropathic pain

73% of payers reported high unmet needs.[a†]

Top identified needs

n = 29[a‡]

1. More effective analgesia (66%)
2. Reduced side effects (28%)
3. New class of pain medication (21%)
4. Lower abuse potential (17%)

> **"For chronic forms of pain, there is a need for new medications that aren't long-acting, have better safety profiles, and don't pose the risk of addiction."**
>
> —Pharmacy director, MCO

*When thinking about the category of pain management, where do you see the greatest unmet needs? Please select all that apply.

†Please rate, on a scale of 1 to 7, how much unmet need there is for acute nociceptive, chronic nociceptive, and neuropathic pain.

‡Please describe the unmet needs you believe exist for acute nociceptive, chronic nociceptive, and neuropathic pain. [Open-ended.]

[a]Includes payers who rated the level of unmet need for each type of pain a 5, 6, or 7 on a scale of 1 to 7. A rating of 5 represented "somewhat high unmet need."

Abbreviation: ADFs, abuse-deterrent formulations.

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THE COST OF PAIN

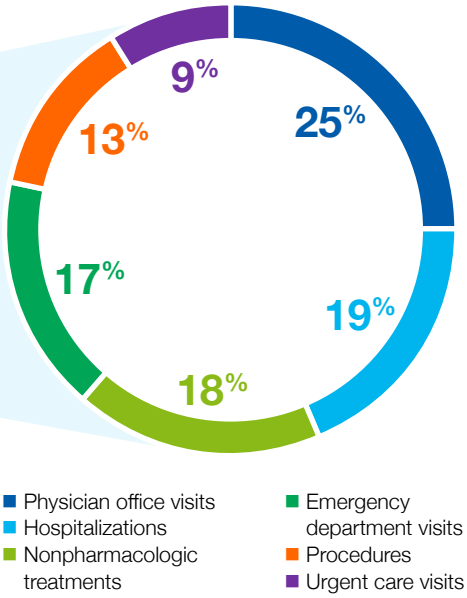
Though pain is an expensive category for payers, it is not one of the most costly categories that they manage. Most payers reported that pain falls between the top 11 and 25 categories in terms of organizational spend across pharmacy and medical benefits.* Pain is often treated concomitantly with other medical conditions, such as cancers and neurological conditions. Therefore, some pain management costs may be included in other disease categories, making the pain category appear less expensive overall.

Breakdown of pain costs†

52% Pharmacy costs

48% Medical costs

Breakdown of medical costs‡



Expenses leading to highest PMPM costs§

1. **Hospital admissions** (78%)
2. **Emergency department visits** (75%)
3. **Drug costs** (58%)

Most MCO respondents are not analyzing pain expenses based on the specific type of pain. However, of those who do track this information, MCOs representing 82% of lives reported that chronic nociceptive pain leads to the most healthcare utilization, such as hospital stays, emergency department or nonroutine physician visits, and pharmacy costs.‖

*Thinking about your organization's total spend on the pain category (including both medical and pharmaceutical costs), where would you estimate this category falls in your organization's spend relative to other categories?

†Thinking about the total spend associated with the pain category, please provide an estimate of how much is attributed to medical vs pharmaceutical costs. Please have total equal 100%.

‡Please provide an estimate of the breakdown of the medical costs associated with the pain category. Please have total equal 100%.

§Which of the following expenses associated with treatment within the pain category produce the highest PMPM costs to your organization? Please rank your top 3 choices.

‖When thinking about the different types of pain, which types of pain result in the most healthcare utilization?

Abbreviation: PMPM, per member per month.

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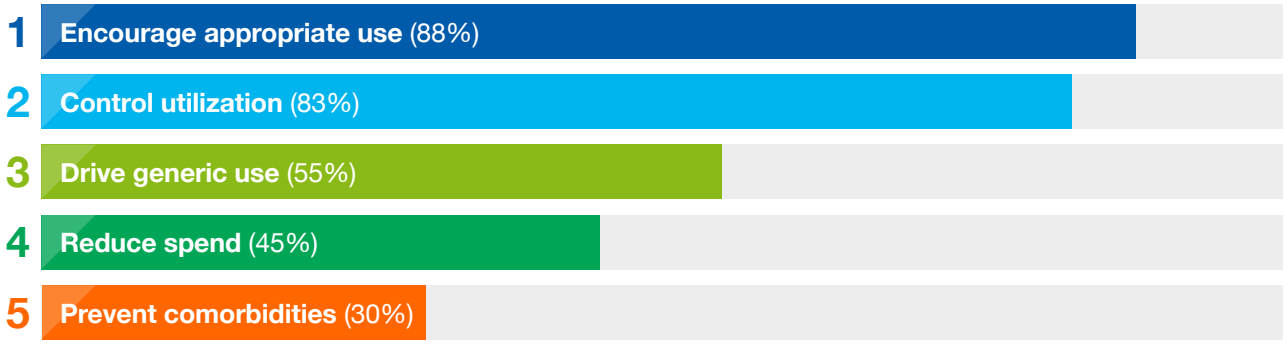
MANAGEMENT OF THE PAIN CATEGORY

Many payers are setting organizational goals specific to pain management in an attempt to control costs associated with the pain category. A large majority of payers now prioritize encouraging appropriate use and controlling utilization of medications.

Top organizational goals for managing pain*



Formulary management

One way to meet pain management goals is through formulary management and utilization criteria. Utilization management strategies vary across pain drug classes and between MCOs and IDNs (see table below). In general, IDNs tend to have fewer restrictions, but for both MCOs and IDNs, quantity limits are some of the most common restrictions across the categories of pain products.

Management of common nonspecialty pain medications†

	Quantity limits		Prior authorizations[a]		Step edits[b]		NDC blocks		No restrictions	
	MCO	IDN	MCO	IDN	MCO	IDN	MCO	IDN	MCO	IDN
Generic opioids	88%	40%	11%	0%	2%	20%	1%	0%	11%	40%
Branded non-ADFs	76%	30%	24%	40%	39%	30%	4%	10%	11%	20%
ADFs	85%	40%	20%	40%	56%	30%	1%	0%	13%	30%
Neuropathic pain medications	65%	10%	7%	10%	5%	20%	1%	0%	35%	60%

Among MCOs who use step edits for ADFs, the majority use a step edit through preferred brands as opposed to generics. For IDNs, the most common prior authorization criterion is for prescriber specialty.

*Which of the following organizational objectives does your organization use for managing patients with pain? Please select all that apply.

†Which of the following restrictions does your organization currently have in place for each of the following classes of nonspecialty medications in the pain category? Please select all that apply. (MCO data are by lives.)

[a]For diagnosis, prescriber specialty, or other.

[b]Through a generic or a preferred brand.

Abbreviation: NDC, National Drug Code.

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MANAGEMENT OF THE PAIN CATEGORY (cont'd)

Alongside utilization management, payers employ other strategies to manage the cost of prescription pain medications. MCOs and IDNs reported different approaches to address and reduce these costs.

Top MCO strategies*

80% use joint management across pharmacy and medical benefits.

78% provide case management for selected patients on pain medication.

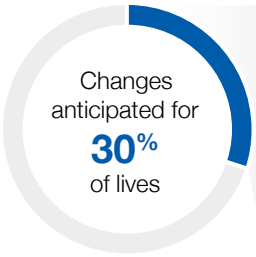
72% cover nonprescription therapies.

Top IDN strategies*

50%

- involve pharmacists in data reconciliation for pain prescriptions
- provide wellness and well-being initiatives
- provide coverage for pain services (eg, referral to a pain management specialist)
- provide counseling to reduce the risk of abuse
- provide partial-fill program to reduce waste

As the focus on pain treatments increases, it would seem likely that payers would change their management of the pain category in the near future. However, MCOs representing 70% of covered lives indicated that they did not anticipate making any management changes in the following calendar year.† For the remaining 30% of covered lives, MCOs anticipated changes related to increasing management and tighter restrictions.



Anticipated management changes‡

n = 58,305,000 lives

- **86%** New quantity limits
- **66%** New prior authorizations
- **64%** Increased restrictiveness on current prior authorizations
- **63%** Addition of step edits associated with access to certain products or classes
- **41%** Increased number of closed formularies
- **27%** New NDC blocks
- **20%** New step edits, either through a generic or preferred product

*In addition to formulary status, what are some of the ways your organization is managing costs for prescription pain medications? Please select all that apply. (MCO data are by lives.)

†Do you expect that your organization's management of the pain category will change within the next calendar year?

‡Which of the following changes do you expect your organization to implement within the next year in this category? Please select all that apply.

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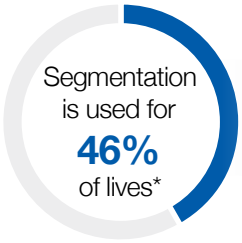
MANAGEMENT OF THE PAIN CATEGORY (cont'd)

Segmentation

Payers often use segmentation to manage high-spend disease categories: a trend that is growing in the pain category.



Changing trends

In the first edition of the report, payers representing only 17% of lives had segmentation for pain patients.

Reason to segment pain patients*

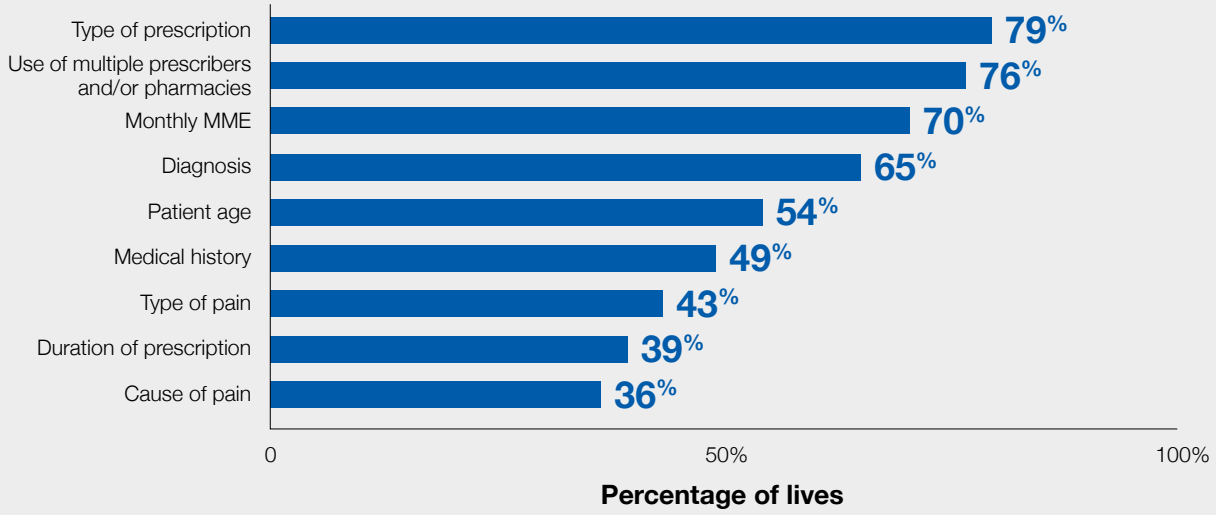
n = 89,479,200 lives

39% As part of patient costs/claims analyses

25% For case management interventions (eg, for chronic pain or high-spend patients)

13% Based on patient history of abuse

Characteristics used to segment pain patients†



As shown on page 17, payers commonly reported placing quantity limits on prescription pain medications in the hope of reducing the amount of pain medications prescribed and to comply with state legislation that limits opioid prescribing. In line with this strategy, among those who segment pain patients, MCOs representing 70% of lives reported segmenting patients based on monthly MME doses. This may not come as a surprise considering that in 2016, the CDC published recommendations that limit daily opioid doses to <90 MME.

*Within the category of pain, does your organization segment or stratify patients by any types of characteristics/profiles and manage them differently? Please select all that apply.

†Which of the following best describes the characteristics your organization uses to segment patients with pain? Please select all that apply.

Abbreviation: MME, morphine milligram equivalent.

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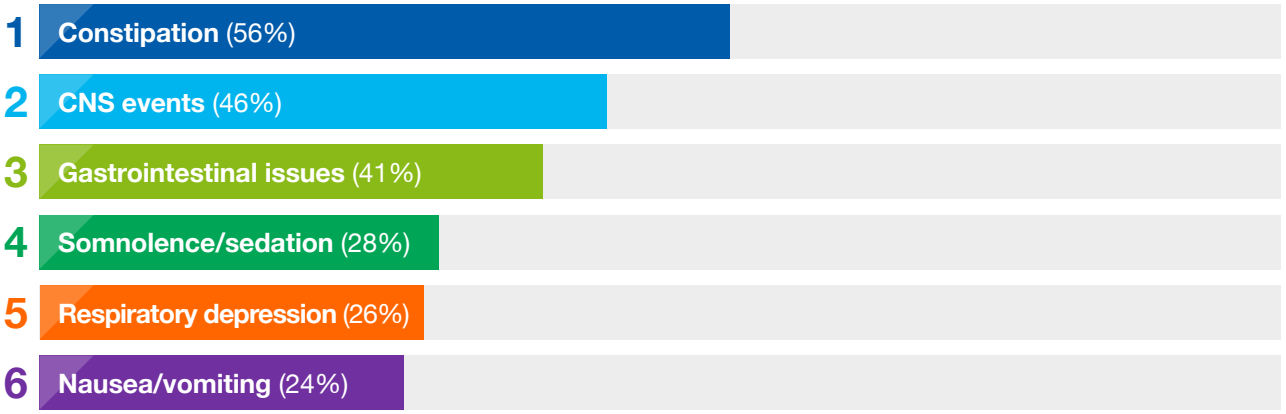
SIDE EFFECTS OF PAIN MEDICATIONS

Patients may experience a wide range of side effects from pain medications. Payers identified reducing these side effects as an important and concerning unmet need, especially for treatments for chronic nociceptive and neuropathic pain.[a]

Top side effects of concern[a*]



Clinician perspective

Similar to payers, surveyed clinicians also reported reduced side effects as an important unmet need. However, clinicians' level of concern for certain side effects differed from payers' level of concern.

Side effects of concern to clinicians[†]

N = 169 clinicians

Somnolence (69%)

Constipation (63%)

Respiratory depression (60%)

Nausea (37%)

Ability to stay awake while seated (33%)

For more information on the clinician perspective, see page 39.

*Please rate, on a scale of 1 to 7, how concerning each side effect is that you identified.

†Please select the top 5 side effects that you are most concerned about in patients receiving pharmacologic treatments for pain. [Clinicians.]

[a]Includes respondents who rated their level of concern as a 5, 6, or 7 on a scale of 1 to 7.

Abbreviation: CNS, central nervous system.

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OPIOID MANAGEMENT AND ADDRESSING ABUSE

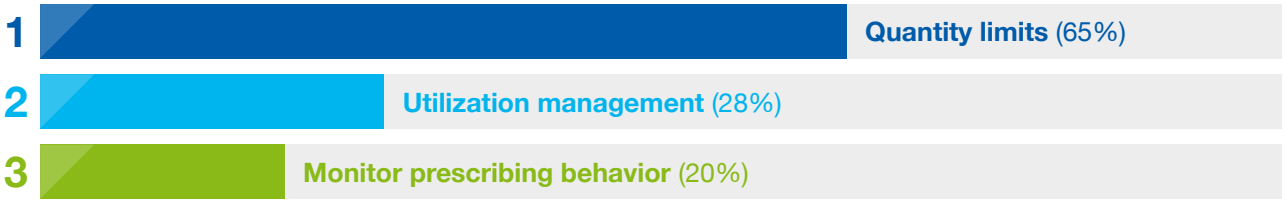
One major challenge that all pain management stakeholders face is addressing opioid abuse. Payers recognize the importance of using opioids to treat pain; however, nearly all are concerned about abuse and diversion. To address this issue, payers have implemented different strategies in hopes of allowing providers to adequately treat legitimate pain while limiting the potential for abuse and diversion.

86% of payers indicated that **opioids have an important role in pain management.[a*]**

98% of payers **expressed concern about abuse.[a*]**

96% of payers **expressed concern about diversion.[a*]**

Top efforts to minimize opioid abuse[†]



Payers use a variety of utilization management strategies in an effort to minimize abuse. Commonly reported strategies include prior authorizations, step edits, and specialist requirements (eg, limiting long-term use of opioids to pain specialists). To monitor prescribing behavior, some payers reported using physician scorecards or implementing various programs to identify high-volume prescribers.

Payers are not alone in their efforts to minimize opioid abuse and diversion. Some state governments are passing laws that limit the number of days for an initial opioid prescription or the amount of opioid that can be dispensed. Many payers follow these legislation and marketplace changes closely, as they are often responsible for implementing policies to enforce the legislation.

MCOs representing **52% of lives** are following upcoming legislation or marketplace changes.[‡]

55% of payers actively monitor the opioid class.[§]

> **"Quantity limits on opioid prescriptions have a role at both the institution and state levels. It may be too early to see the effects of 7-day prescribing limits for acute pain, but quantity limits definitely have a place in addressing abuse."**
>
> —Pharmacy director, IDN

*Please rate, on a scale of 1 to 7, how important opioids are in the treatment of pain management and how concerned you are about abuse and diversion.

†Please describe the steps your organization is taking to minimize abuse of prescription pain medications. [Open-ended.]

‡Are you actively following any of the possible upcoming legislation or marketplace changes that could impact the pain category?

§Please list which classes of pain products you actively monitor. [Open-ended.]

[a]Includes payers who rated the importance/concern of opioids as a 5, 6, or 7 on a scale of 1 to 7.

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OPIOID MANAGEMENT AND ADDRESSING ABUSE (cont'd)

The role of abuse-deterrent formulations

ADFs are products designed to deter manipulation and abuse of opioids through various methods, such as physical or chemical barriers, opioid antagonists, or aversive agents.

A number of ADFs have received approval in recent years, and many stakeholders are quickly educating themselves on the products. Eighty-three percent of payers rated themselves as knowledgeable of the existing ADFs; however, questions remain about the ability of ADFs to reduce opioid abuse.[a*] Overall, only 36% of payers rated currently available ADFs as being effective in reducing abuse.[b†] Though payers rated additional ADFs as an important unmet need, it is unclear if this is because they do not believe the current ADFs can reduce abuse or if they are looking for more price competition to lower the overall costs of these branded agents.

58% of payers responded that developing additional ADFs was among the greatest unmet needs in general pain management.[‡]

86% of payers responded that they believe it is important for patients to have access to ADFs,[c§] and a third also selected greater access as a top unmet need.[‡] However, many payers reported restricted access to these branded agents, with MCOs implementing step edits through preferred brands for 46% of lives.

FDA guidance

Though ADFs are not abuse proof, the FDA expects these products to play an important role in addressing prescription drug abuse and has encouraged their development. In 2015, the FDA issued guidance for manufacturers on how to test the abuse-deterrent properties of medications seeking ADF designation. The guidance has helped ensure that the abuse-deterrent properties of ADFs are tested in a uniform manner.

58% of payers rate themselves as knowledgeable of the FDA guidance.[a‖]

88% of payers believe it is important for manufacturers to follow the FDA guidance for evaluating ADFs.[c#]

Unlike payers, clinicians are less knowledgeable of both ADFs and the FDA guidance. Only 38% of clinicians rated themselves as knowledgeable of ADFs in general,[a] and 26% rated themselves as not at all knowledgeable of the FDA guidance.[‖] This trend may help explain why 20% of clinicians reported not prescribing ADFs to any of their opioid-treated patients.** For more information on the clinician perspective, please see page 36.

More recently, in November 2017, the FDA published a second guidance that encourages the development of generic ADFs. This guidance likely reflects the FDA's desire to provide less expensive abuse-deterrent options than the current branded agents.

*Please rate, on a scale of 1 to 7, how knowledgeable you are with the available ADFs.

†Please rate, on a scale of 1 to 7, how effective you believe ADFs are in reducing opioid abuse.

‡When thinking about the category of pain management, where do you see the greatest unmet needs? Please select all that apply.

§Please rate, on a scale of 1 to 7, how important it is that patients have access to ADFs.

‖Please rate, on a scale of 1 to 7, how knowledgeable you are with the FDA guidance on evaluation and labeling of ADFs.

#Please rate, on a scale of 1 to 7, how important it is to you that opioid manufacturers follow the FDA guidance and recommendations for evaluating ADFs.

**If a patient requires an opioid, what percentage of the time do you prescribe an ADF? [Clinicians.]

[a]Includes respondents who rated their level of knowledge as a 5, 6, or 7 on a scale of 1 to 7.

[b]Includes payers who rated the level of effectiveness as a 5, 6, or 7 on a scale of 1 to 7.

[c]Includes respondents who rated the level of importance as a 5, 6, or 7 on a scale of 1 to 7.

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NEUROPATHIC PAIN

Neuropathic pain remains an area with significant unmet needs, as 83% of payers rated ineffective analgesia as the most concerning issue related to treating neuropathic pain. This concern ranked significantly higher than other issues, including difficulty in diagnosing the pain (15%), medication side effects (13%), and abuse of neuropathic pain agents (5%).*

Payers are covering a variety of treatments for neuropathic pain, though on average, both payers and clinicians rate these options as only moderately effective.† In general, payers have fewer restrictions for neuropathic pain agents compared to other pain drug classes.

For 35% of lives, MCOs have no restrictions for neuropathic pain agents.‡

60% of IDNs have no restrictions for neuropathic pain agents.‡

Though payers provide coverage for multiple drug treatments for the different types of neuropathic pain, clinicians use anticonvulsants and antidepressants more than other drug options. For more information on the clinician perspective of neuropathic pain, please see page 37.

	Covered for >50% of lives§ (n varies by response)	Used by >50% of clinicians‖ (n varies by response)
Anticonvulsants	✔	✔
Antidepressants	✔	✔
NSAIDs	✔	
Opioids	✔	
Local anesthetics	✔	

When looking at the different forms of neuropathic pain, payer coverage for diabetic peripheral neuropathic pain and postherpetic neuralgia was fairly similar, with the greatest coverage for anticonvulsants and NSAIDs for both conditions.

Coverage of medications used to treat diabetic peripheral neuropathic pain§

- Anticonvulsants (99%)
- NSAIDs (95%)
- Antidepressants (89%)
- Opioids (81%)
- Local anesthetics (70%)

Coverage of medications used to treat postherpetic neuralgia§

- NSAIDs (94%)
- Anticonvulsants (87%)
- Antidepressants (86%)
- Local anesthetics (81%)
- Opioids (75%)

*Please describe what you think are the most concerning issues related to neuropathic pain. [Open-ended.]

†Please rate, on a scale of 1 to 7, how effective you think the current treatment options are for neuropathic pain overall.

‡Which of the following restrictions does your organization currently have in place for each of the following classes of nonspecialty medications in the pain category? Please check all that apply.

§Please select the treatment options that you cover for patients with the following types of neuropathic pain. Please select all that apply. (MCO data are by lives.)

‖Please select the treatments that you use to treat patients with the following types of neuropathic pain. Please select all that apply. [Clinicians.]

Abbreviation: NSAIDs, nonsteroidal anti-inflammatory drugs.

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NEUROPATHIC PAIN (cont'd)

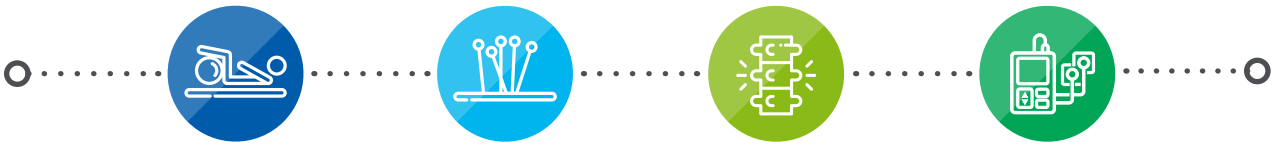
Nonpharmacologic treatments

While coverage of neuropathic pain medications is fairly widespread across the different drug classes, payers provide the least amount of coverage for nonpharmacologic pain treatments. This trend may be related to payers' belief that these treatments are suboptimally effective, as no payers reported any of these options as being very effective.*

Payers representing less than 50% of lives report covering nonpharmacologic treatments for the various types of neuropathic pain, and similarly, fewer than 50% of clinicians use nonpharmacologic options during treatment.[†]

Top nonpharmacologic treatments covered[‡]

n = 29



Physical therapy (45%)

Acupuncture (45%)

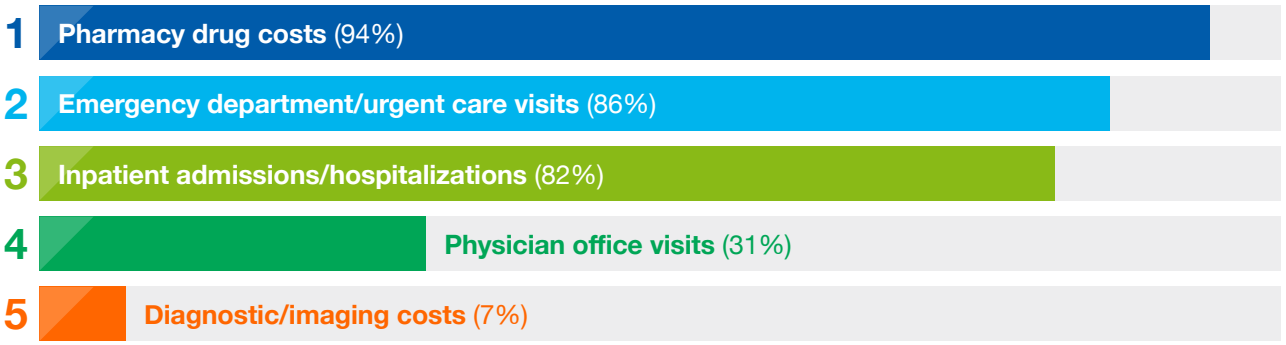
Chiropractic visits (31%)

TENS/electrical stimulation (21%)

Financial impact

For 59% of lives, MCOs rated neuropathic pain as having only "some" financial impact; however, MCOs representing 26% of covered lives reported that treating neuropathic pain has a significant financial impact on their plan.[a§]

Biggest cost drivers for patients with neuropathic pain[‖]



*Of the nonpharmacologic treatments you cover, please rate, using a scale of 1 to 7, how effective you think each is in treating neuropathic pain.

[†]Please select the treatments that you use to treat patients with the following types of neuropathic pain. Please select all that apply. [Clinicians.]

[‡]Please list the nonpharmacologic treatments that you cover for neuropathic pain. [Open-ended.]

[§]Please rate, using a scale of 1 to 7, the financial impact of treating neuropathic pain patients on your plan.

[‖]Which of the following are the biggest cost drivers for patients with neuropathic pain? (MCO data are by lives.)

[a]Includes payers who rated the financial impact as a 5, 6, or 7 on a scale of 1 to 7.

Abbreviation: TENS, transcutaneous electrical nerve stimulation.

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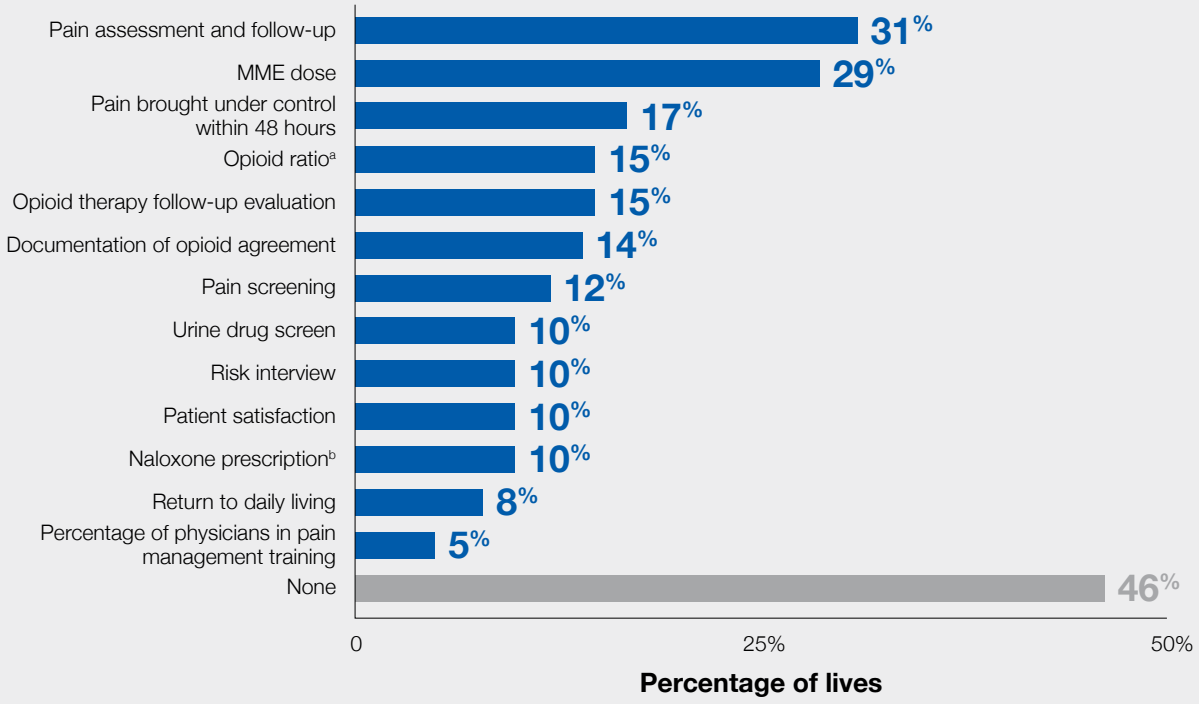
QUALITY METRICS

More than half of MCOs (representing 89,700,000 lives) reported that they track pain-related quality metrics. The most commonly tracked metric was pain assessment and follow-up, closely followed by MME doses prescribed.

Pain-related quality metrics tracked by lives*



Quality metrics do not have a significant impact on physician reimbursement; most MCOs and IDNs reported that <20% of their payments are tied to quality metrics. This aligns with the fact that the majority of clinicians reported that <20% of their reimbursement is based on quality metrics.[†] While reimbursement may not be a reason to track quality metrics, many payers must track them for compliance and other reasons.

Top factors influencing selection of quality metrics[‡]

n = 105,040,800 lives

56% Ability to influence/change

56% NCQA/HEDIS requirements

48% Listing in MIPS

37% CMS Stars Rating requirement

36% Impact on budget

*Which of the following quality metrics related to the pain category does your plan track, if any? Please select all that apply.

[†]What percentage of the payments to your network providers/outpatient payments/reimbursement is impacted by quality metrics?

[‡]How do you select which pain-related quality metrics to track?

[a]Ratio of opioid vs non-opioid pain management prescriptions.

[b]Percentage of patients with chronic pain who receive opioid prescriptions and also receive naloxone prescriptions.

Abbreviations: CMS, Centers for Medicare and Medicaid Services; HEDIS, Healthcare Effectiveness Data and Information Set; MIPS, Merit-based Incentive Payment System; NCQA, National Committee for Quality Assurance.

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QUALITY METRICS (cont'd)

Clinician perspective

Like payers, many clinicians track various quality metrics related to pain. The most commonly tracked quality metric by clinicians is patient satisfaction, which is only tracked by payers representing 10% of covered lives. Many clinicians track patient satisfaction ratings because they may impact reimbursement. However, effective January 2018, HCAHPS patient satisfaction scores for pain are no longer tied to reimbursement, which may result in changes to the tracking of this metric. For more information on the clinician perspective, please see page 40.

Overall, payers rated tracking quality metrics as moderately impactful within their plans.*

Impact of tracking pain-related quality metrics†

n = 36

- **Decreased number of patients on high doses of opioids** (72%)
- **Improved patient safety** (56%)
- **Reduced overall healthcare costs** (53%)
- **Increased quality rating** (33%)
- **Improved patient outcomes** (25%)

Though payers primarily use data from quality metrics to make policy updates and train staff and providers, they report a wide variety of ways that they use the data.

Most common uses of data from pain-related quality metrics‡

n = 36

1. Policy updates (69%)
2. • Provider training (42%)
   • Staff training (42%)
3. • Decision-making on coverage (36%)
   • Reporting to NCQA or CMS (36%)
   • Member education (36%)
4. Claims filing/processing (17%)
5. Reimbursement projections (14%)

*How impactful has tracking pain-related quality measures been on your organization?

†What kind of impact has tracking pain-related quality measures had on your organization? Please select all that apply.

‡How do you use the data from your pain-related quality metrics? Please select all that apply.

Abbreviation: HCAHPS, Hospital Consumer Assessment of Healthcare Providers and Systems.

Clinicians

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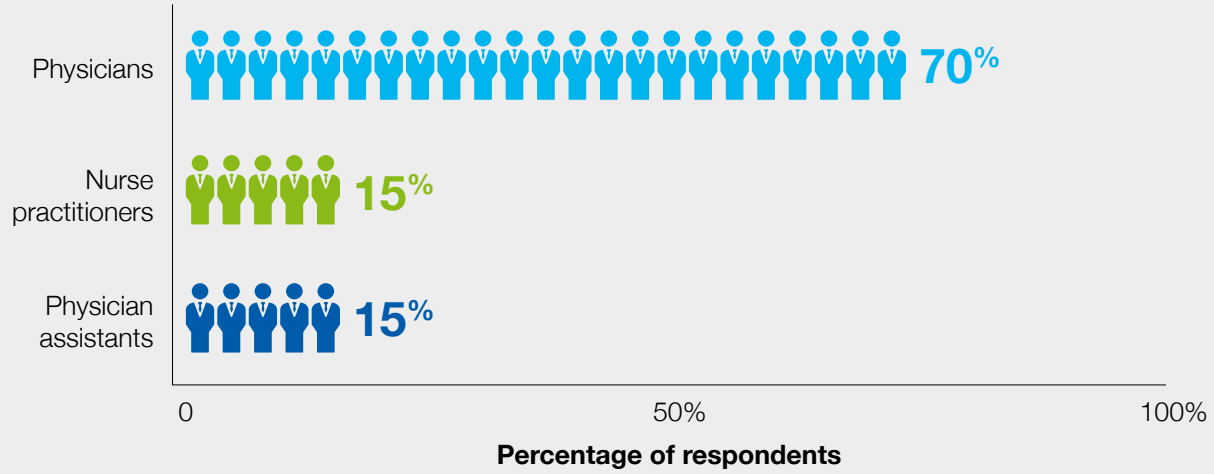
INTRODUCTION

Clinicians are on the front lines of pain management. They face the difficult task of balancing treatment and minimizing the risks of abuse, diversion, and addiction. Clinicians of different specialties treat patients with pain, ranging from orthopedic surgeons who manage acute postoperative pain to pain management specialists who treat patients with chronic pain.

CLINICIAN DEMOGRAPHICS

Respondent roles*
N = 169 clinicians



Throughout this chapter, data are displayed for the full sample (N = 169 clinicians) with the exception of data that reflect responses from only a subset of respondents, in which case the n value is displayed.

Average number of patients treated for pain:

132 per month

Forty-nine of the 50 surveyed nurse practitioners and physician assistants have prescribing authority, either independently or under physician supervision, resulting in a total of 168 clinicians with prescribing authority.† Questions related to prescribing were asked of these 168 clinicians, and their responses are shared throughout this chapter.

Throughout this chapter, totals may not equal 100% due to rounding.

*What is your role in your practice?

†In your state, please select the option that best describes your prescribing authority.

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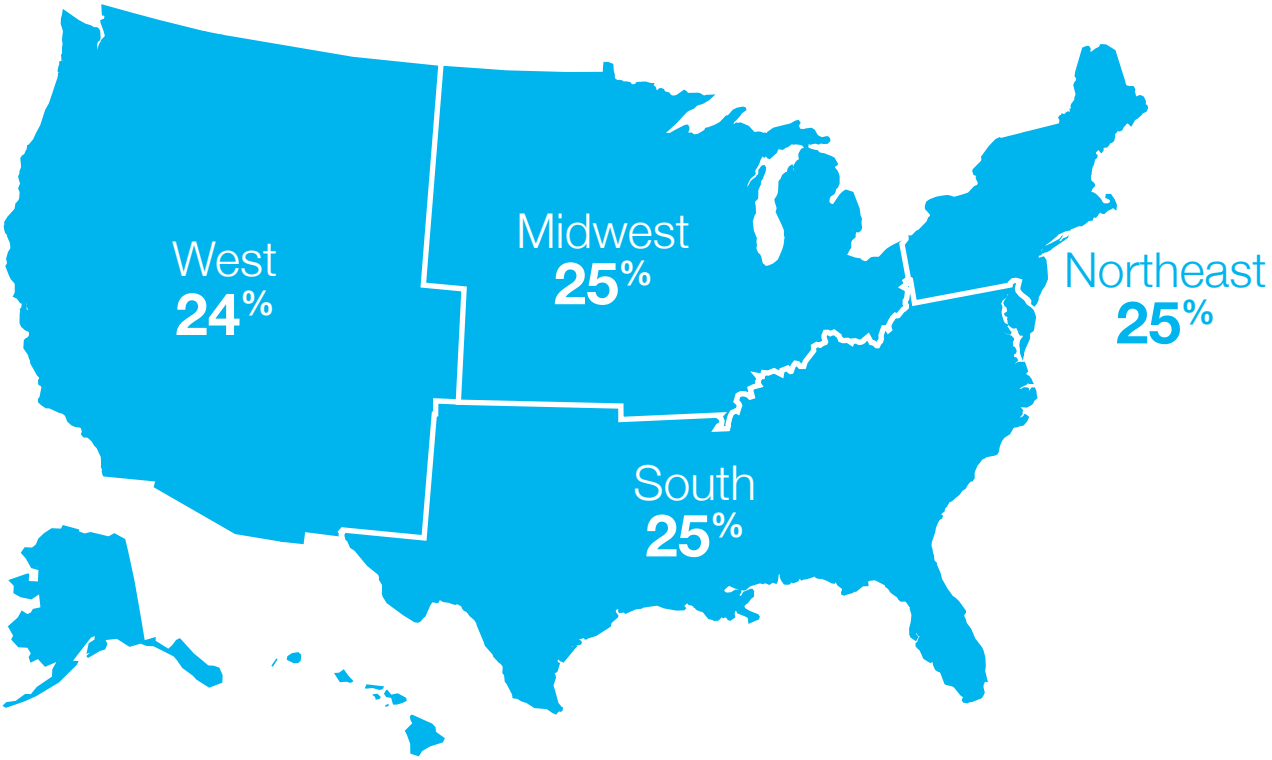
CLINICIAN DEMOGRAPHICS (cont'd)

Clinician specialties represented[a]

- **18%** Pain management
- **18%** Primary care/ internal medicine
- **12%** Oncology
- **11%** Orthopedics
- **9%** Neurology
- **9%** PM&R
- **9%** General surgery
- **9%** Emergency department
- **5%** Plastic surgery

Regions represented*



*What state is your practice in?

[a]Based on primary and secondary specialties.

Abbreviation: PM&R, physical medicine and rehabilitation.

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UNMET NEEDS

Across the different types of pain (eg, acute nociceptive, chronic nociceptive, and neuropathic pain), many clinicians perceive a need for more effective treatments. Additionally, more clinicians reported a higher level of unmet need for chronic nociceptive pain and neuropathic pain than they did for acute nociceptive pain. Similar to payers, clinicians also cited unmet needs in addressing the potential for abuse of pain medications.

Greatest unmet needs in pain management*

53% Additional ADFs

52% New class of pharmaceutical pain medication

47% More effective analgesia

47% Reduced side effects

40% Greater access to existing ADFs

Acute nociceptive pain

69% of clinicians reported high unmet needs for acute nociceptive pain.[a†]

Top identified needs[a‡]

n = 112[a]

1. More effective analgesia (44%)
2. Lower abuse potential (35%)
3. Reduced side effects (24%)
4. New class of pain medication (13%)

Chronic nociceptive pain

89% of clinicians reported high unmet needs for chronic nociceptive pain.[a†]

Top identified needs[a‡]

n = 148[a]

1. More effective analgesia (39%)
2. Lower abuse potential (32%)
3. New class of pain medication (20%)
4. Reduced side effects (15%)

Neuropathic pain

81% of clinicians reported high unmet needs for neuropathic pain.[a†]

Top identified needs[a‡]

n = 135[a]

1. More effective analgesia (63%)
2. Reduced side effects (18%)
3. New class of pain medication (14%)
4. Lower abuse potential (10%)

> **"We can usually intervene and do something for acute pain or make it at least tolerable for the patient, but when the pain becomes chronic, be it nociceptive or neuropathic, that really starts to be a big issue."**
>
> —Nurse practitioner, pain management

*When thinking about the category of pain management, where do you see the greatest unmet needs? Please select all that apply.

†Please rate, on a scale of 1 to 7, how much unmet need there is for acute nociceptive, chronic nociceptive, and neuropathic pain.

‡Please describe the unmet needs you believe exist for acute nociceptive, chronic nociceptive, and neuropathic pain. [Open-ended.]

[a]Includes clinicians who rated the level of unmet need for each type of pain a 5, 6, or 7 on a scale of 1 to 7. A rating of 5 represented "somewhat high unmet need."

Abbreviation: ADFs, abuse-deterrent formulations.

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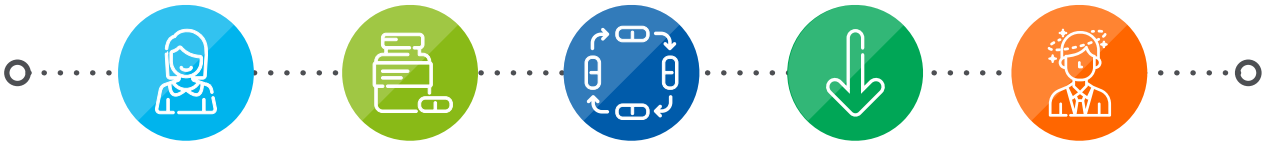
TREATMENT CONSIDERATIONS

Given the high prevalence of pain and concerns about the safety of certain medications, clinicians must make well-informed prescribing decisions. Clinicians reported that tolerability, efficacy, and safety were the most important factors when selecting a pain medication.

Most important attributes of a treatment[a]*



Tolerable (97%)

Effective in managing pain (96%)

Can be used concomitantly with other medications (96%)

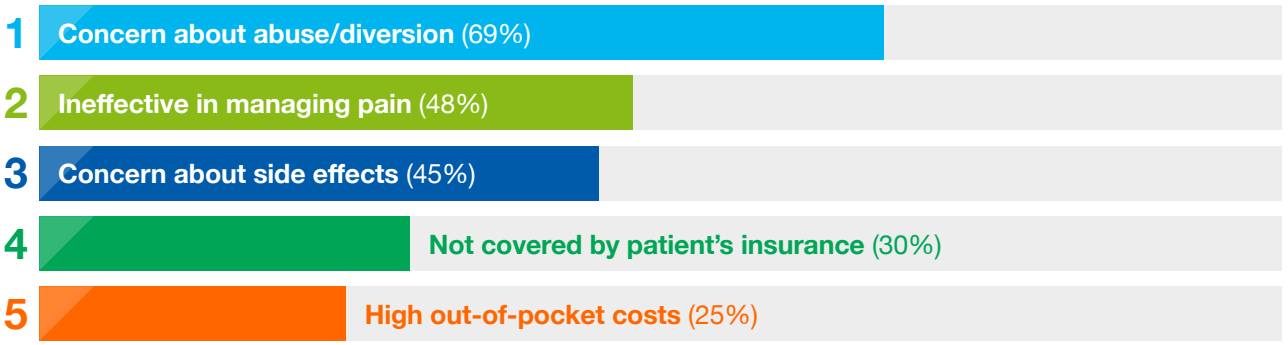
Low potential for abuse (91%)

Low rate of discontinuation due to side effects (86%)

In addition to the attributes listed above, payer policies and out-of-pocket patient costs are also important to clinicians. Nearly half of clinicians reported insurance coverage as a very important attribute in making pain treatment decisions, and 39% reported affordable copays as very important.

When asked about reasons for not prescribing a pain medication, the majority of clinicians reported concern about abuse and diversion as the top factor.

Most common reasons to not prescribe a pain medication[†]



*Please rate, on a scale of 1 to 7, the following product attributes on their importance to your treatment decisions for a patient with pain.

[†]Which of the following factors most frequently cause you to decide not to prescribe a particular acute or chronic pain treatment? Please select all that apply.

[a]Includes clinicians who rated the importance as a 5, 6, or 7 on a scale of 1 to 7.

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PRESCRIBING TRENDS

As a general trend, clinicians are writing opioid prescriptions for shorter lengths of time and for smaller doses, reducing the overall amount of opioids prescribed. This trend likely reflects clinicians' concern about prescription drug abuse, regulatory scrutiny, and desire to adhere to guidelines, such as the CDC guidelines and state legislation that limits opioid prescribing. For example, the CDC guidelines recommend limiting daily opioid doses to <90 MME as well as using other pharmacologic agents besides opioids to manage neuropathic pain. Fifty-two percent of clinicians in the survey reported being knowledgeable of these particular guidelines.[a*]

Changes in prescribing by pain type[†]

Acute nociceptive pain

Increase:

- NSAIDs (55%)
- Acetaminophen (45%)
- ADFs (27%)

Decrease:

- Short-acting opioids (69%)
- Length of opioid prescriptions (60%)
- Long-acting opioids (53%)
- Daily MME (45%)

Chronic nociceptive pain

Increase:

- NSAIDs (47%)
- Acetaminophen (34%)
- ADFs (26%)

Decrease:

- Short-acting opioids (67%)
- Long-acting opioids (49%)
- Length of opioid prescriptions (46%)
- Daily MME (40%)

Neuropathic pain

Increase:

- NSAIDs (29%)
- Acetaminophen (20%)
- ADFs (17%)

Decrease:

- Short-acting opioids (51%)
- Long-acting opioids (42%)
- Daily MME (33%)
- Length of opioid prescriptions (31%)

Across all pain types, the most pronounced change in prescribing was reduced prescribing of short-acting opioids. Many clinicians have also decreased their daily dosage (MME) of opioids for the various types of pain. Along with concerns about patient safety and the risk of abuse, this change could also be related to state restrictions on MME and the fact that some payers are now monitoring MME doses within their plans.

MCOs representing 29% of covered lives are **tracking MME doses.**

Though a handful of clinicians reported increases in ADF prescribing, more clinicians reported increased use of NSAIDs and acetaminophen. This could be related to tighter payer restrictions on ADFs compared with these other treatments (as described on page 17 in the Payers chapter). However, when asked about future prescribing changes, increased prescribing of NSAIDs, acetaminophen, and ADFs was anticipated by roughly the same number of clinicians (within each pain type).

Changing trends

Clinicians are now tracking legislation and marketplace changes more closely. Thirty-nine percent of clinicians are tracking these changes versus just 25% in the previous report.[‡]

*How knowledgeable are you with the CDC Guideline for Prescribing Opioids for Chronic Pain?

[†]Please select the statement(s) from below that best describes how your prescribing for acute nociceptive pain, chronic nociceptive pain, and neuropathic pain has changed, if at all, over the last 2 to 3 years. Please select all that apply.

[‡]Are you actively following any of the possible upcoming legislation or marketplace changes that could impact the pain category?

[a]Includes respondents who rated their level of knowledge as a 5, 6, or 7 on a scale of 1 to 7.

Abbreviations: MME, morphine milligram equivalent; NSAIDs, nonsteroidal anti-inflammatory drugs.

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OPIOID PRESCRIBING AND ADDRESSING ABUSE

Seventy-two percent of clinicians believe that opioids are important in treating pain[a*]; however, many clinicians express concern about abuse and diversion of pain medications. Due to these concerns, clinicians employ a variety of strategies in an attempt to prevent abuse, and as previously mentioned, many have also changed their prescribing behavior.

Concern regarding short- and long-acting opioids[b†]

>80% of clinicians are concerned about abuse.

~70% of clinicians are concerned about diversion.

Opioid prescribing for acute and chronic pain

Clinicians of certain specialties are more likely to prescribe opioids than others due to the type of pain patients they treat. For example, pain management and oncology specialists prescribe more opioids for chronic pain compared with other specialists.

Clinician specialty	Percentage of patients prescribed an opioid for acute pain‡	Percentage of patients prescribed an opioid for chronic pain‡
Neurology (n = 15)	44%	24%
Orthopedics (n = 18)	**60%**	23%
Pain management (n = 30)	42%	**47%**
Primary care/internal medicine (n = 30)	35%	**35%**
PM&R (n = 15)	41%	26%
Oncology (n = 21)	46%	**47%**
General surgery (n = 16)	**78%**	27%
Emergency department (n = 16)	43%	19%
Plastic surgery (n = 8)	**88%**	26%

On average across specialties,

49% of patients are prescribed an opioid for acute pain.‡

33% of patients are prescribed an opioid for chronic pain.‡

*Please rate, on a scale of 1 to 7, how important opioids are in the treatment of pain.

†Please rate, on a scale of 1 to 7, how concerned you are about abuse/diversion for each of the following classes of medications within the pain category.

‡For patients with acute and chronic nociceptive pain, what percentage of the time do you prescribe an opioid?

[a]Includes clinicians who rated the importance as a 5, 6, or 7 on a scale of 1 to 7.

[b]Includes clinicians who rated their level of concern as a 5, 6, or 7 on a scale of 1 to 7.

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OPIOID PRESCRIBING AND ADDRESSING ABUSE (cont'd)

Initial opioid prescriptions

Some clinicians are concerned about prescribing an opioid at an initial patient visit due to the potential for "doctor shopping." Fifty-five percent of clinicians are not willing to prescribe opioids during an initial patient visit,* and many report having made changes to their prescribing behavior. These changes include prescribing smaller quantities of opioids for a patient's initial prescription.

61% of clinicians have shortened the duration of initial opioid prescriptions over the past 2 years. On average, **prescriptions are shorter by 8.5 days** (n = 97).†

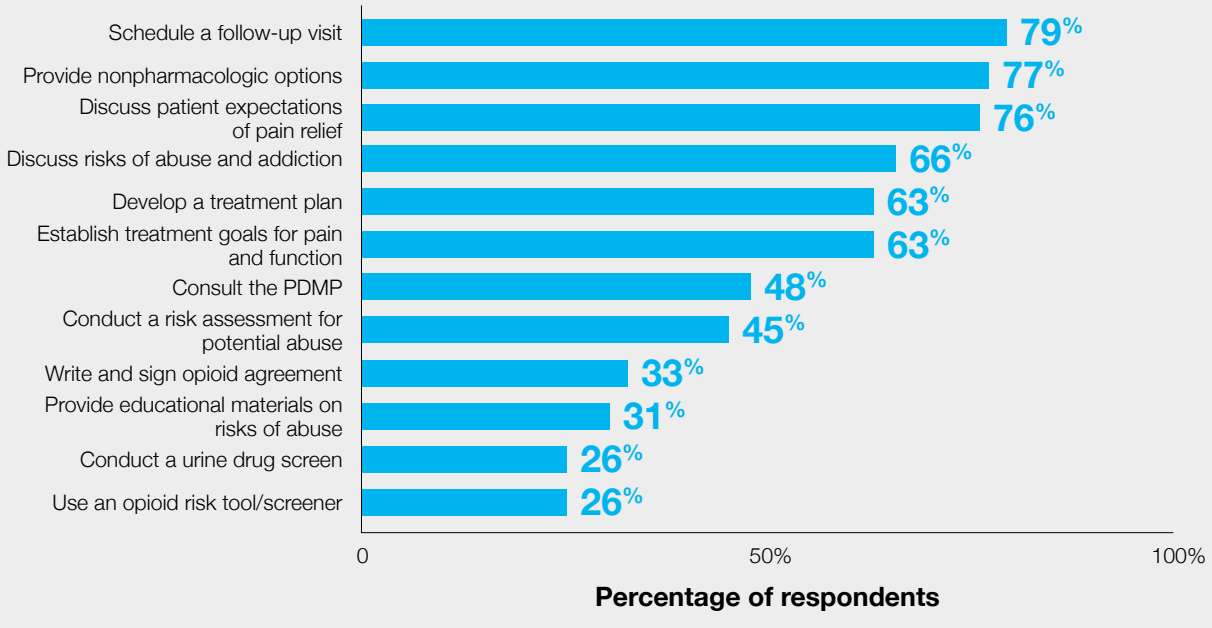
Average duration of initial opioid prescription§

Of those clinicians who reported changing the length of their initial opioid prescriptions in the past 2 years, 60% indicated that concern about opioid abuse was a primary reason for the change. However, some clinicians also cited legislation (23%) and more education (11%) as other factors impacting their prescribing behavior (n = 99).‡

9.7 days for acute pain **24.8** days for chronic pain

When starting patients on an opioid, it is important for clinicians to set patient expectations, assess the potential for opioid abuse, and counsel on safe drug storage to avoid diversion. There are a variety of steps that clinicians take to ensure safety when writing a patient's initial opioid prescription.

Frequent practices when writing initial opioid prescription‖



*Do you prescribe opioids during the first visit with a patient?

†Has the duration of an initial prescription changed over the past 2 years, and is the duration shorter or longer? (Average number of days.)

‡What has impacted that change? [Open-ended.]

§What is the average duration of a typical initial opioid prescription that you write?

‖When writing an initial opioid prescription, which of the following do you do? Please select all that apply.

Abbreviation: PDMP, prescription drug monitoring program.

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OPIOID PRESCRIBING AND ADDRESSING ABUSE (cont'd)

Clinicians of certain specialties are more likely to use tools to screen for potential abuse. For example, 70% of pain management specialists and 66% of PCPs/internists reported that they frequently conduct abuse/addiction screenings when writing opioid prescriptions, whereas only 12% of those in general surgery and 10% of those in orthopedics reported frequently conducting these types of screenings.[a*] Along with these types of screenings, many clinicians also consult PDMPs when prescribing opioids.

"When prescribing an opioid, you need to gather as much information about the patient as possible. You need to have the tools, such as urine screens, opioid agreements, and opioid risk stratifications ready."

—Physician, anesthesiology

PDMPs

PDMPs are statewide electronic databases that track prescriptions for controlled substances, providing clinicians the ability to check whether patients are obtaining prescriptions from multiple providers or pharmacies. Many stakeholders in both healthcare and government believe that PDMPs are important tools that can help providers more safely prescribe opioids. Based on the survey results, 33% of all prescribing clinicians indicated that they always check the PDMP prior to writing an opioid prescription,[†] and 61% of clinicians reported increased usage of PDMPs over the past year: 17% started checking it, and 44% checked it more frequently.[‡] It is possible that these changes may be related to concerns about abuse and/or new state legislation requirements, although 28% of clinicians were unsure whether or not their state had specific mandates regarding PDMP consultation.[§] As of January 2018, 39 states have enacted legislation that requires clinicians to query PDMPS, though the specific situations for which checks are necessary vary by state.

Overall, 48% of prescribing clinicians reported checking PDMPs when writing an initial opioid prescription; however, clinicians of certain specialties may be more likely to query the PDMP than others. For example, 75% of emergency department clinicians reported using PDMPs, whereas just 33% of neurologists and 24% and oncologists reported checking PDMPs when writing initial opioid prescriptions. These differences between specialists may be due to the fact that many states do not require PDMP checks for patients receiving opioids for cancer-related pain or those in hospice care.

Clinicians who check PDMPs most often when writing initial opioid prescriptions

Emergency department (75% check PDMP)

Pain management (70% check PDMP)

Primary care/ internal medicine (67% check PDMP)

*How often do you conduct a substance abuse/addiction screening prior to prescribing an opioid?

†How often do you check PDMPs prior to prescribing an opioid?

‡How has your use of the PDMP changed in the past year?

§Is consulting the PDMP required by your state?

[a]Includes respondents who rated frequency as a 5, 6, or 7 on a scale of 1 to 7.

Abbreviation: PCPs, primary care physicians.

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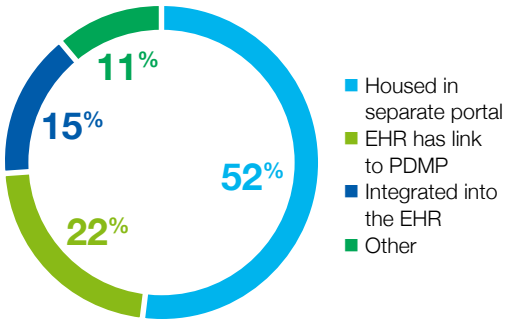
OPIOID PRESCRIBING AND ADDRESSING ABUSE (cont'd)

Depending on the state's system, PDMPs can be accessed in a variety of ways. However, 32% of clinicians reported that consulting the PDMP is not at all easy without interrupting patient visit or workflow.*

Method of accessing PDMP†



Drug-seeking behavior

Eighty-one percent of clinicians who work in emergency departments rated that they often encounter drug-seeking behavior.[a‡] Utilization of PDMPs may be high in emergency departments because they can help clinicians identify patients who have received opioid prescriptions from multiple providers.

Treating overdose

Some clinicians may also have to treat patients who have overdosed. For clinicians who treat these patients, many refer the patient to substance abuse treatment and/or for psychological evaluation as well as schedule follow-up appointments with the patient.

Follow-up care for opioid overdoses§

n = 107

1. **Refer patient to substance abuse treatment** (74%)
2. **Refer patient for psychological evaluation** (58%)
3. **Schedule a follow-up visit** (55%)
4. **Write a naloxone prescription for the patient** (26%)
5. **Write a prescription for buprenorphine or other MAT** (17%)
6. **Write a naloxone prescription for the patient's relative** (14%)

Continuing education

Clinician education around appropriate opioid prescribing, screening for potential abuse, and preventing doctor shopping has been identified as a key component in minimizing opioid abuse. Sixty-seven percent of clinicians have taken continuing education classes related to abuse of prescription pain medications. Twenty percent report that they took a state-required continuing education class, but only 8% have taken classes specifically about safe prescribing.‖

*Please rate, on a scale of 1 to 7, how easy it is to consult the PDMP without interrupting the patient visit or workflow.

†How do you access the PDMP in your practice?

‡Please rate, on a scale of 1 to 7, how often you encounter patients who exhibit drug-seeking behavior in your clinical practice.

§If you treat a patient for an opioid overdose, what do you do to ensure the patient receives appropriate follow-up care? Please select all that apply. [Thirty-seven percent of surveyed clinicians reported that they do not treat overdoses.]

‖Please describe any required continuing education classes that you have taken in the past year related to abuse of prescription pain medications. [Open-ended.]

[a]Includes clinicians who rated the frequency as a 5, 6, or 7 on a scale of 1 to 7.

Abbreviations: EHR, electronic health record; MAT, medication-assisted treatment.

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OPIOID PRESCRIBING AND ADDRESSING ABUSE (cont'd)

The role of abuse-deterrent formulations

ADFs are products designed to deter opioid abuse through a variety of strategies, including physical or chemical barriers, opioid antagonists, or aversive agents. Though ADFs are not abuse proof, the FDA expects these products to play an important role in addressing prescription drug abuse. Like payers, many clinicians identified an unmet need for additional ADFs.

Close to half of clinicians selected additional ADFs (53%) and greater patient access to existing ADFs (40%) as the greatest unmet needs in pain management. However, only 38% of clinicians rated themselves as being knowledgeable of ADFs,[a*] and only 28% of clinicians rated the current ADFs as being effective at reducing opioid abuse.[b†]

ADF prescribing

On average, clinicians estimated that nearly 25% of their patients receive ADFs, but 20% of clinicians reported that they do not prescribe ADFs at all.[‡] When looking at ADF prescribing by specialty, clinicians specializing in pain management/pain medicine and neurology prescribe ADFs to a higher percentage of their patients than do clinicians of other specialties. Conversely, clinicians in general surgery tend to prescribe ADFs to a smaller number of patients.

Percentage of patients taking opioids who receive ADFs[‡]

39% **of patients** (pain management)

13% **of patients** (general surgery)

Top factors impacting decision to prescribe an ADF[§]

1. Risk of abuse (42%)
2. Patient pain profile (21%)
3. Access (11%)
4. Length of prescription (10%)
5. Cost (7%)

FDA guidance

In 2015, the FDA published guidance for manufacturers to encourage the development of ADFs. Only 22% of clinicians rated themselves as knowledgeable about the guidance, and 26% rated themselves as not at all knowledgeable.[a‖] This level of familiarity differed from that of payers, 58% of whom responded that they were knowledgeable of the guidance.[a‖] This contrast may suggest that payers rely on the guidance to make formulary decisions more than clinicians rely on it to make prescribing decisions. For more information on the payer perspective, see page 22.

*Please rate, on a scale of 1 to 7, how knowledgeable you are with the available ADFs.

†Please rate, on a scale of 1 to 7, how effective you believe ADFs are at reducing opioid abuse.

‡If a patient requires an opioid, what percentage of the time do you prescribe an ADF?

§How do you decide whether or not to prescribe an ADF? [Open-ended.]

‖Please rate, on a scale of 1 to 7, how knowledgeable you are with the FDA guidance on evaluation and labeling of ADFs.

[a]Includes respondents who rated their level of knowledge as a 5, 6, or 7 on a scale of 1 to 7.

[b]Includes respondents who rated the effectiveness as a 5, 6, or 7 on a scale of 1 to 7.

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NEUROPATHIC PAIN

Unlike nociceptive pain, neuropathic pain may involve damage to the nerves. Clinicians who treat patients with neuropathic pain overwhelmingly agree that there is a need for more effective treatment options, and, on average, they rated neuropathic pain treatments as less than moderately effective.

Two common forms of neuropathic pain that arise from medical conditions include diabetic peripheral neuropathic pain and postherpetic neuralgia. For these types of neuropathy, many clinicians prescribe anticonvulsants and antidepressants, which they also rated as being the most effective.

Drug treatments for common types of neuralgia

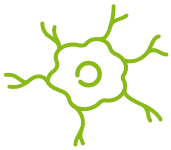
n varies by response

Treatments for diabetic peripheral neuropathic pain*

- Anticonvulsants (69%)
- Antidepressants (67%)
- NSAIDs (43%)
- Local anesthetics (39%)
- Opioids (27%)

Most effective treatments for diabetic peripheral neuropathic pain[a†]

- Anticonvulsants (49%)
- Antidepressants (37%)
- Local anesthetics (25%)
- Opioids (22%)
- NSAIDs (14%)



Treatments for postherpetic neuralgia*

- Anticonvulsants (57%)
- Antidepressants (49%)
- Local anesthetics (46%)
- Opioids (38%)
- NSAIDs (35%)

Most effective treatments for postherpetic neuralgia[a‡]

- Anticonvulsants (57%)
- Antidepressants (46%)
- Local anesthetics (37%)
- Opioids (36%)
- NSAIDs (21%)

Opioids for neuropathic pain

For diabetic peripheral neuropathic pain, 59% of clinicians rated opioids as less than moderately effective,[b] and only 27% of clinicians reported using opioids to treat this form of pain. For postherpetic neuralgia, 38% of clinicians reported using opioids. Although certain opioids may be effective at providing pain relief early on in neuropathic pain treatment, the CDC guidelines do not recommend opioids as a first- or second-line medication for neuropathic pain. This may explain why some clinicians favor other drug treatments over opioids when treating patients with neuralgia.

*Please select the treatments that you use to treat patients with the following types of neuropathic pain. Please select all that apply.

†Please rate, on a scale of 1 to 7, how effective you think each of the following treatments is for diabetic peripheral neuropathic pain.

‡Please rate, on a scale of 1 to 7, how effective you think each of the following treatments is for postherpetic neuralgia.

[a]Includes clinicians who rated the effectiveness as a 5, 6, or 7 on a scale of 1 to 7.

[b]Includes clinicians who rated the effectiveness as a 1, 2, or 3 on a scale of 1 to 7.

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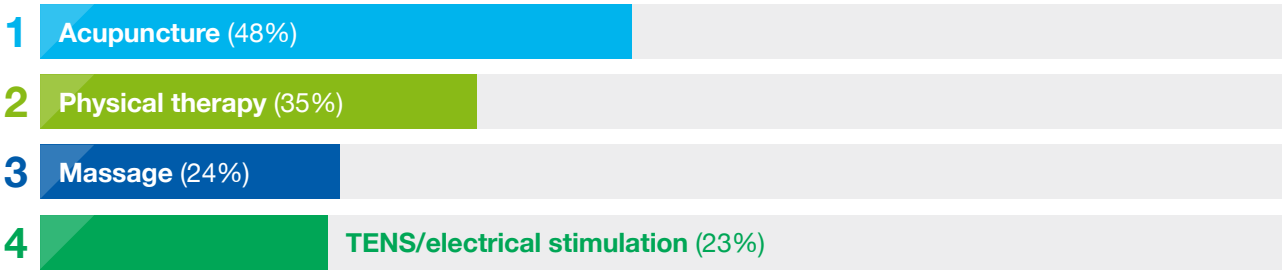
NEUROPATHIC PAIN (cont'd)

Nonpharmacologic treatments

Various guidelines and recommendations suggest a multimodal approach to neuropathic pain management. This includes both pharmacologic and nonpharmacologic interventions. Approximately 40% of clinicians prescribed nonpharmacologic treatments for their patients with neuropathic pain.

Top nonpharmacologic treatment options used for neuropathic pain*

n = 86



Though clinicians prescribe these nonpharmacologic treatments, they rate them as suboptimally effective.

Effectiveness of nonpharmacologic treatment options used for neuropathic pain†

n varies by response

TENS/electrical stimulation
Effective[a]: 40%
Fairly ineffective[b]: 15%

Acupuncture
Effective[a]: 34%
Fairly ineffective[b]: 36%

Physical therapy
Effective[a]: 27%
Fairly ineffective[b]: 30%

Massage
Effective[a]: 24%
Fairly ineffective[b]: 57%

> **"Neuropathic pain tends to be severe and chronic. There is no good algorithm for treatment because everyone responds differently. There is a need for a wider variety of choices to treat it, because right now, treatment is mostly just trial and error."**
>
> —Physician, neurology

*Please list the nonpharmacologic treatments that you prescribe for patients with neuropathic pain. [Open-ended.]

†Please rate, on a scale of 1 to 7, how effective you think each of the following nonpharmacologic treatments is at treating neuropathic pain.

[a]Includes clinicians who rated the effectiveness as a 5, 6, or 7 on a scale of 1 to 7.

[b]Includes clinicians who rated the effectiveness as a 1, 2, or 3 on a scale of 1 to 7.

Abbreviation: TENS, transcutaneous electrical nerve stimulation.

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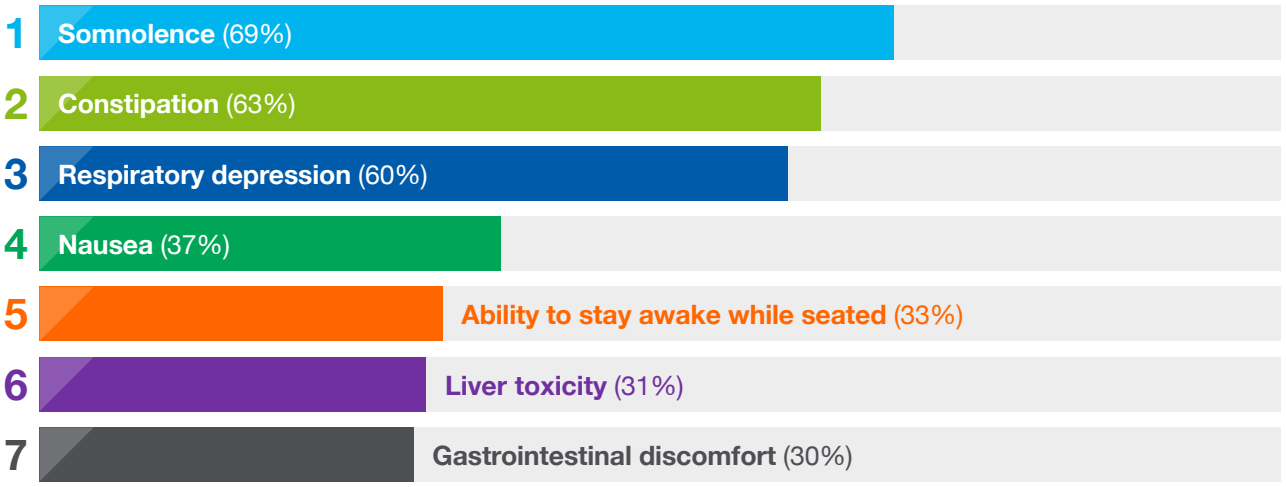
SIDE EFFECTS OF PAIN MEDICATIONS

Side effects from medications can often make pain management difficult or lead to problems with adherence. Though clinicians cited issues in other areas of pain management as more pressing, 47% of clinicians selected reduced side effects as one of the greatest unmet needs in pain management, and among those clinicians, 93% expressed a high degree of concern.[a]

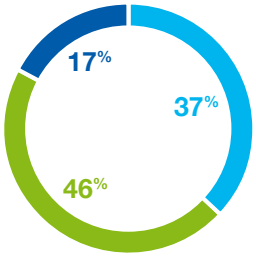
Side effects of greatest concern[b]*



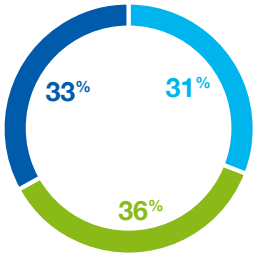
Side effects can lead to a variety of complications in pain management. They may cause a clinician to switch a patient's pain medication if the patient's safety or ability to tolerate the medication is at risk. Side effects may also cause additional office visits or, in extreme scenarios, emergency department visits. Complete discontinuation of pain therapy because of side effects is also a possibility.

Complications due to side effects[†]

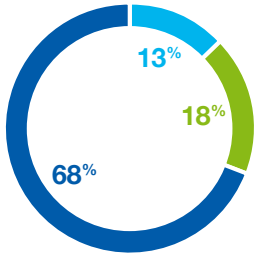
Medication switches[c]



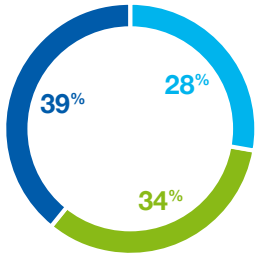
Additional office visits[c]



Emergency department visits[c]



Discontinuation of pain treatment[c]



■ Often ■ Sometimes ■ Rarely

*Please select the top 5 side effects that you are most concerned about in patients receiving pharmacologic treatments for pain.

[†]On a scale of 1 to 7, how often do side effects from pain products cause you to switch your patient's pain medication, result in additional office visits, result in visits to the emergency department, and cause you to stop your patient's pain therapy?

[a]Includes clinicians who rated their level of concern as a 5, 6, or 7 on a scale of 1 to 7.

[b]Additional side effects of concern included the inability to concentrate (29%), asthenia (27%), gastrointestinal bleeding (26%), dizziness (24%), renal toxicity (24%), vomiting (24%), blurred vision (7%), weight gain (5%), pruritus (5%), hypertension (5%), other (4%), and edema (1%).

[c]"Often" refers to clinicians who rated the frequency as a 5, 6, or 7 on a scale of 1 to 7; "sometimes" refers to clinicians who rated the frequency as a 4 on a scale of 1 to 7; "rarely" refers to clinicians who rated the frequency as a 1, 2, or 3 on a scale of 1 to 7.

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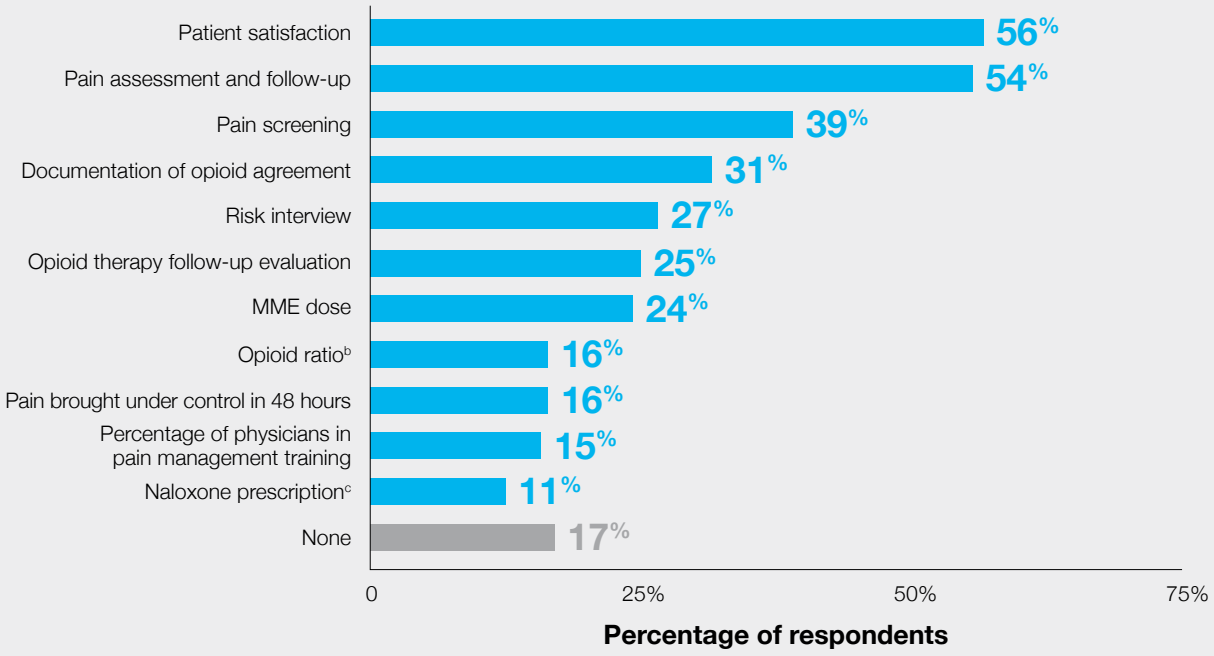
QUALITY METRICS

Many payers and clinicians are tracking quality metrics, some of which are specific to pain management. With a shift toward value-based care and public campaigns to stop treating pain as the "fifth vital sign," the role of quality metrics, and the importance of certain metrics, may start to change among payers and clinicians. Now that HCAHPS patient satisfaction scores for pain are no longer tied to clinician reimbursement (effective January 2018), it is possible that hospitals may not track patient satisfaction as closely.[a]

Pain-related quality metrics tracked*



Top factors influencing selection of quality metrics†

56% Patient satisfaction ratings

40% Ability to influence/change

26% Impact on reimbursement

18% Help with assessing training needs

15% Listing in MIPS

Clinicians had varied opinions on the importance of tracking quality metrics, with 40% rating them as important and 41% rating them as not very important.[d] This may be due to the fact that not all clinicians have their reimbursement tied to quality metrics, as is the case for 36% of surveyed clinicians. Another 37% of clinicians indicated that only up to 20% of their reimbursement is based on quality metrics.‡ This aligns with payer responses, which indicated that <20% of payments are tied to quality metrics.

*Which of the following quality metrics related to the pain category does your practice track, if any? Please select all that apply.

†How do you select which pain-related quality metrics to track?

‡What percentage of your practice's reimbursement is based on quality metrics?

[a]HCAHPS was developed based on a partnership between the Centers for Medicare and Medicaid Services and the Agency for Healthcare Research and Quality.

[b]Ratio of opioid prescriptions issued versus non-opioid pain management prescriptions.

[c]Percentage of patients with chronic pain who receive opioid prescriptions and also receive naloxone prescriptions.

[d]Includes clinicians who rated the importance as a 5, 6, or 7 on a scale of 1 to 7 and a 1, 2, or 3 on a scale of 1 to 7, respectively.

Abbreviations: HCAHPS, Hospital Consumer Assessment of Healthcare Providers and Systems; MIPS, Merit-based Incentive Payment System.

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IMPACT OF PAYER MANAGEMENT ON PRACTICES

Payer management continues to increase across all therapeutic areas, including pain. These changes require clinicians to deal with various requirements and constraints, which may impact practice policy and staffing. Clinicians estimate that only 23% of their pain prescriptions are branded medications.* However, when they do prescribe branded agents, they frequently encounter restrictions that may differ by plan.

Most common restrictions encountered when prescribing branded pain medications[a†]

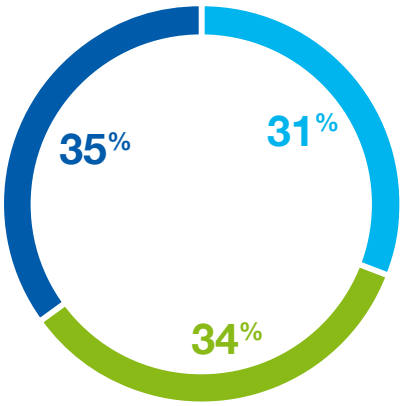
n = 135

1. Prior authorizations for diagnosis (45%)
2. Step edits through generics (42%)
3. Quantity limits (38%)
4. Step edits through preferred brands (36%)
5. Prior authorizations for prescriber specialty (32%)

Prior authorizations

Prior authorizations, particularly those for diagnoses, are commonly used by payers to manage the pain category. In some cases, practices have additional staff to handle these prior authorizations.

Staff to handle prior authorizations[‡]



- Staff spends >50% of their time handling prior authorizations
- Staff spends ≤50% of their time handling prior authorizations
- No staff to handle prior authorizations

Forty-nine percent of clinicians rated prior authorizations as influential on their prescribing decisions.[b§] When clinicians encounter a prior authorization requirement for a branded pain medication, they prescribe another medication approximately 45% of the time.[‖] When a medication is denied (eg, the product is not covered or the utilization management criteria is not fulfilled), 74% of clinicians report that they frequently prescribe another product.[a#]

*Of the prescriptions you write for pain medications, please estimate the percentage of branded and generic medications.

†How often do you encounter each of the following restrictions when prescribing a branded pain medication?

‡Do you have staff in your office whose role is to handle prior authorizations for patients (ie, complete the prior authorization paperwork, manage process)?

§Please rate, on a scale of 1 to 7, how influential the requirement of completing a prior authorization is on your prescribing decisions for pain medications.

‖When you encounter a prior authorization requirement for a branded pain medication, what percentage of the time do you do each of the following?

#When a pain product you have prescribed is denied by a patient's insurance company, how often do you take each of the following courses of action?

[a]Includes clinicians who rated the frequency as a 5, 6, or 7 on a scale of 1 to 7.

[b]Includes clinicians who rated the level of influence as a 5, 6, or 7 on a scale of 1 to 7.

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IMPACT OF PAYER MANAGEMENT ON PRACTICES (cont'd)

Patient costs

Payer management and the emergence of high-deductible health plans are increasing patients' responsibility for drug costs. As a result, some patients are engaging in conversations with clinicians and office staff about the cost of their medications.

~26% of pain patients discuss medication costs with clinicians.*

Practices must be prepared for these conversations and understand what types of financial assistance are available for patients. However, according to the survey, only a small number of patients actually receive copay assistance information from their providers. This may be due to the fact that the pain medication class is highly generic, as clinicians estimated that 77% of the prescriptions they write for pain medications are for generic products.

≤10% The majority of clinicians **provide copay assistance information to ≤10% of patients,** likely due to the low percentage of branded pain prescriptions.†

*What percentage of your patients who experience pain discuss medication costs with you?

†For what percentage of your pain patients do you provide information about product copay assistance offered by the manufacturer?

Employers

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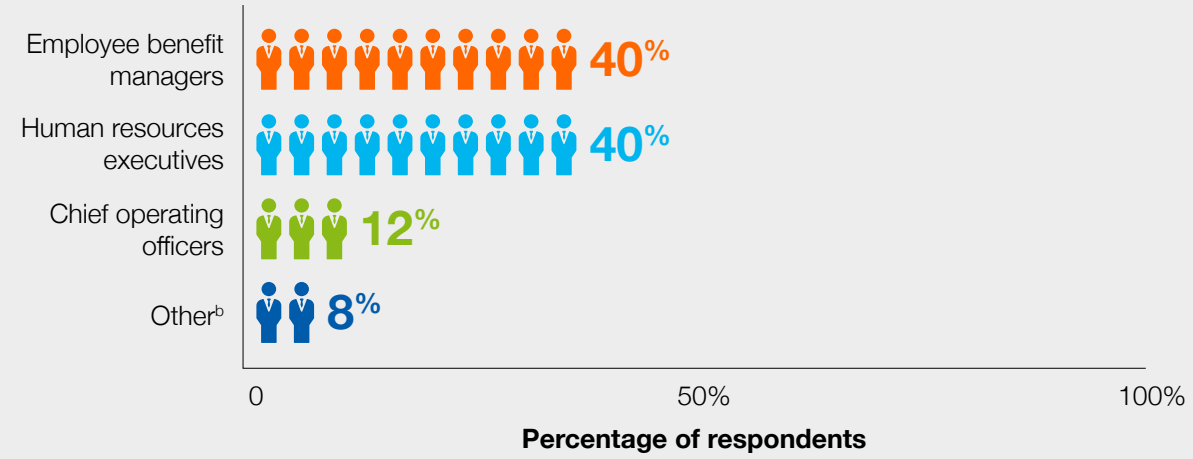
INTRODUCTION

Pain has one of the largest impacts on employers' organizations compared with other therapeutic areas. For example, both direct medical costs and impaired employee productivity from pain can have significant financial implications for employers. This chapter explores the employer perspective of pain management, uncovering the challenges employers face and the various strategies they use to manage the category and control costs. As those who ultimately pay for the vast majority of commercial healthcare, employers provide valuable insight.

EMPLOYER DEMOGRAPHICS

Respondent roles[a]*
N = 25

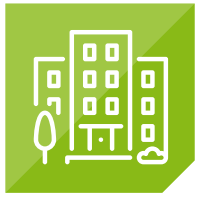


Throughout this chapter, data are displayed for the full sample (N = 25 employers) with the exception of data that reflect responses from only a subset of the full sample, in which case the n value is displayed.

Company size

101-500 employees
32%

501-5000 employees
36%



>5000 employees
32%

*Which of the following best describes your current position?

[a]Employee benefit consultants and other senior executives were not allowed to participate. All participants were screened to ensure that they have a self-insured pharmacy benefit and are involved, experienced, and familiar with that pharmacy benefit.

[b]"Other" included corporate benefit analyst and corporate medical director.

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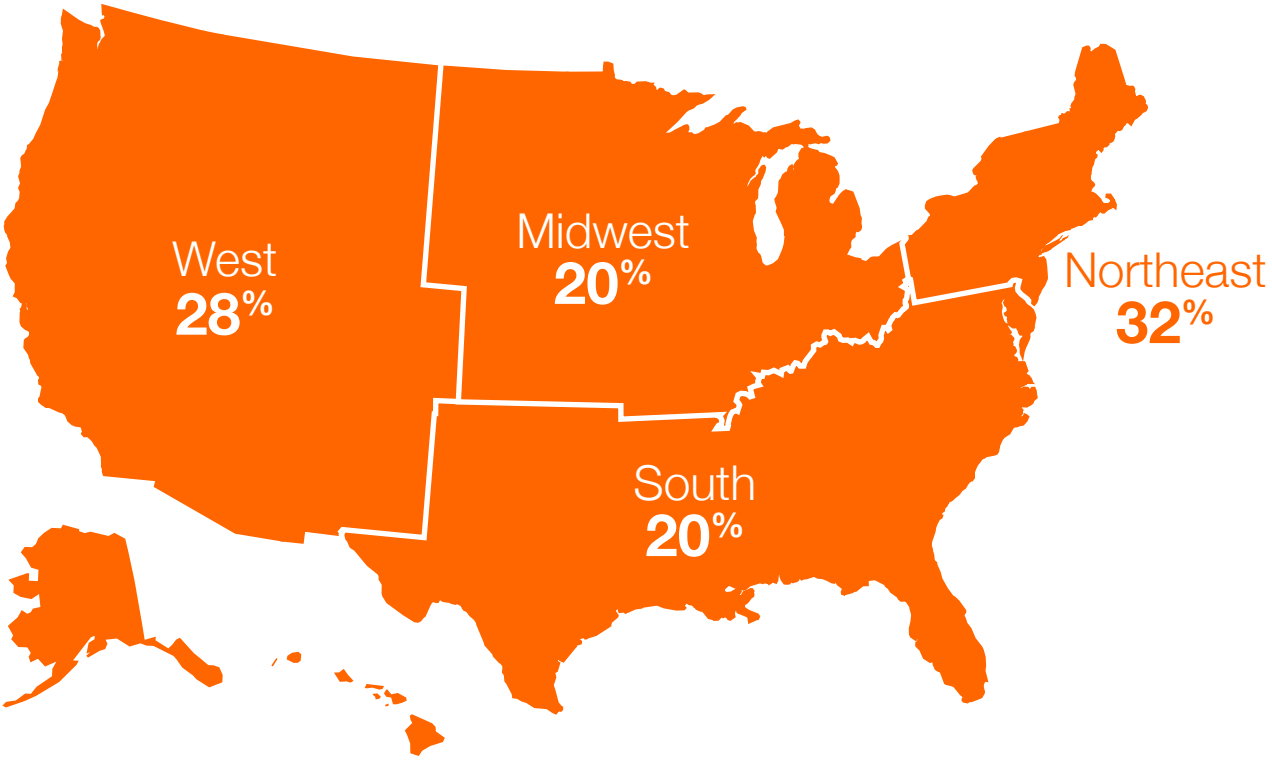
EMPLOYER DEMOGRAPHICS (cont'd)

Industries represented*

- 20% Professional services
- 16% Manufacturing
- 8% Finance
- 8% Healthcare
- 8% Hospitality
- 8% Retail trade
- 8% Technology
- 8% Transportation
- 16% Other[a]

Regions represented†



*In what industry does your organization operate?

†In what state do you work the majority of your time as human resources or benefits manager?

[a]"Other" included construction, education, real estate, and wholesale/distribution.

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CURRENT TRENDS

Many employers are tracking a variety of trends in pain management, especially those relating to prescription drug abuse. Sixty percent of employers reported being concerned about abuse of prescription pain medications, and 44% are concerned about diversion.[a*]

72%
of employers follow legislation and marketplace changes in the pain category.[†]

Top trends tracked[‡]

n = 18

1. Passage of state legislation (67%)
2. • Greater use of ≤14-day refills (61%)
   • FDA approval of ADFs (61%)
3. • Passage of federal legislation (56%)
   • More widespread use of opioids (56%)

Pain management objectives

Perhaps in response to concerns about abuse and misuse of medications, roughly a third of employers reported encouraging appropriate use of medications as a primary organizational objective for pain management. However, 16% of surveyed employers have no primary objective, an increase from just 4% in the previous study period. This change may suggest that employers are now focusing on other therapeutic areas.

Most common primary objectives[§]

1. **Encourage appropriate use** (36%)
2. **Minimize indirect costs (eg, absenteeism)** (20%)
3. **Ensure compliance and persistence** (12%)

*Please rate, on a scale of 1 to 7, how concerned you are about abuse and diversion of prescription pain products.

[†]Do you actively follow any of the possible upcoming legislation or marketplace changes that could impact the pain category (such as the passage of state or federal laws, greater use of ≤14-day refills, or changes to product formulations to prevent abuse or side effects, etc)?

[‡]Which of the following trends in the pain category do you follow closely? Please select all that apply.

[§]What is your organization's primary objective for the pain management category? Please select one.

[a]Includes employers who rated their level of concern as a 5, 6, or 7 on a scale of 1 to 7.

Abbreviation: ADFs, abuse-deterrent formulations.

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THE COST OF PAIN

Costs associated with the pain category can impact employers from a variety of perspectives, including pharmacy spending, the volume of claims, and indirect costs, such as employee productivity. Compared with the previous report, 20% more employers rated pain management as one of the biggest cost drivers in terms of pharmacy spend and volume of claims. In both survey periods, pain management was rated as the number 1 cost driver related to impaired employee productivity.

Therapeutic areas that are the biggest cost drivers*

Pharmacy benefit spend	Volume of claims	Impaired employee productivity
1. Diabetes (76%)	1. Cardiovascular disease (64%)	**1. Pain management (64%)**
2. Cardiovascular disease (52%)	**2. Pain management (56%)**	2. Diabetes (52%)
3. Pain management (48%)	3. Gastrointestinal disease (28%)	3. Cardiovascular disease (40%)

Impaired employee productivity, including absenteeism, has a much more significant financial impact on employers compared with other stakeholders. Sixty-eight percent of employers are at least moderately concerned with their employees' absenteeism rate,[a†] and 44% reported an increase in the percentage of employees who have missed work due to pain management issues in the past 3 years.[b‡] On average, employers estimate that 21% of their company's absenteeism rate is directly related to issues regarding pain.[c§]

Pain management challenges

Employers face a variety of challenges in managing the pain category, particularly those relating to costs from prescription drugs. Employers are also dealing with an aging workforce, which may lead to more employees requiring health services related to pain.

Top challenges in pain management[‖]

1. Increasing prescription costs (52%)
2. • Aging workforce (43%)
   • Educating/engaging employees (43%)
3. Healthcare reform (39%)

*Within your organization, which therapy areas have the highest volume of claims, highest pharmacy benefit spend, and biggest impact on productivity (eg, employees' absenteeism, work performance, etc)? Please rank the top 3 for each.

†Please rate how concerned your company is about your employees' absenteeism rate on a scale of 1 to 7.

‡Please rate, on a scale of 1 to 7, how, if at all, the percentage of employees who have missed work due to pain management issues has changed over the past 3 years.

§Please estimate the percentage of the company's absenteeism rate that is directly related to issues regarding pain.

‖What are the biggest challenges your company currently faces in providing healthcare benefits and programs within the pain management category?

[a]Includes employers who rated the level of concern as a 4, 5, 6, or 7 on a scale of 1 to 7.

[b]Includes employers who rated the level of increase as a 5, 6, or 7 on a scale of 1 to 7.

[c]Mean based on estimates from those who had access to absenteeism data (n = 17).

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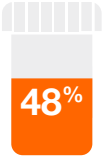
MANAGEMENT OF THE PAIN CATEGORY

Formulary management

As healthcare costs continue to rise, employers are using various formulary management strategies to control costs of prescription pain medications. Depending on cost and other factors, the various drug classes have different levels of restrictions. On average, employers have the most restrictive formularies for ADFs and branded non-abuse-deterrent opioids and the least restrictive formularies for generic opioids and neuropathic pain medications.

Employers reported having far fewer restrictions in place than did payers in the survey. This may be because employers are allowing PBMs or health plans to implement further restrictions. For example, across the 4 drug classes, the most commonly reported restriction by employers was a prior authorization that limits prescribing to clinicians of certain specialties. This formulary strategy differed from that of payers in the survey, who reported quantity limits as the most common restriction across every pain type. This may indicate a tendency among employers to defer to specialists in making appropriate prescribing decisions, whereas payers are more likely to impose prescribing limits themselves.

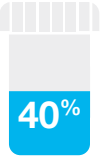
Restrictiveness of formulary and most common restrictions*†



ADFs: 48% of employers have a restrictive formulary.[a]

1. Prior authorization for prescriber specialty (32%)
2. Quantity limits (24%)
3. Step edit through generics (16%)

16% have no restrictions.



Branded non-ADFs: 40% of employers have a restrictive formulary.[a]

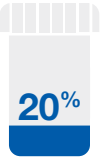
1. Prior authorization for prescriber specialty (44%)
2. Quantity limits (36%)
3. Other prior authorization (20%)

8% have no restrictions.

Generic opioids: 32% of employers have a restrictive formulary.[a]

1. Prior authorization for prescriber specialty (48%)
2. Quantity limits (28%)
3. Other prior authorization (12%)

20% have no restrictions.



Neuropathic pain medications: 20% of employers have a restrictive formulary.[a]

1. Prior authorization for prescriber specialty (32%)
2. Quantity limits (32%)
3. Step edit through preferred brands (12%)

20% have no restrictions.

Employers expect their management of the category to change in the future, with 32% of employers reporting that they are likely to have a preferred ADF on formulary in the next 2 years.‡ This follows a trend seen with payers as more ADFs enter the marketplace.

*Please rate, on a scale of 1 to 7, how restrictive your formulary is for each of the following drug classes.

† Which of the following restrictions does your organization currently have in place for each of the following classes of nonspecialty medications in the pain category? Please select all that apply.

‡Do you anticipate any significant changes to your organization's approach to the management for pain medications in the next 2 years? Please select all that apply.

[a]Includes employers who rated the restrictiveness as a 5, 6, or 7 on a scale of 1 to 7.

Abbreviation: PBMs, pharmacy benefit managers.

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MANAGEMENT OF THE PAIN CATEGORY (cont'd)

Employers often develop their formulary strategies with external help. For example, it is not uncommon for health plans and PBMs to influence employer drug coverage decisions.

Top influencers on drug coverage decisions*

56% Health plans

48% PBMs

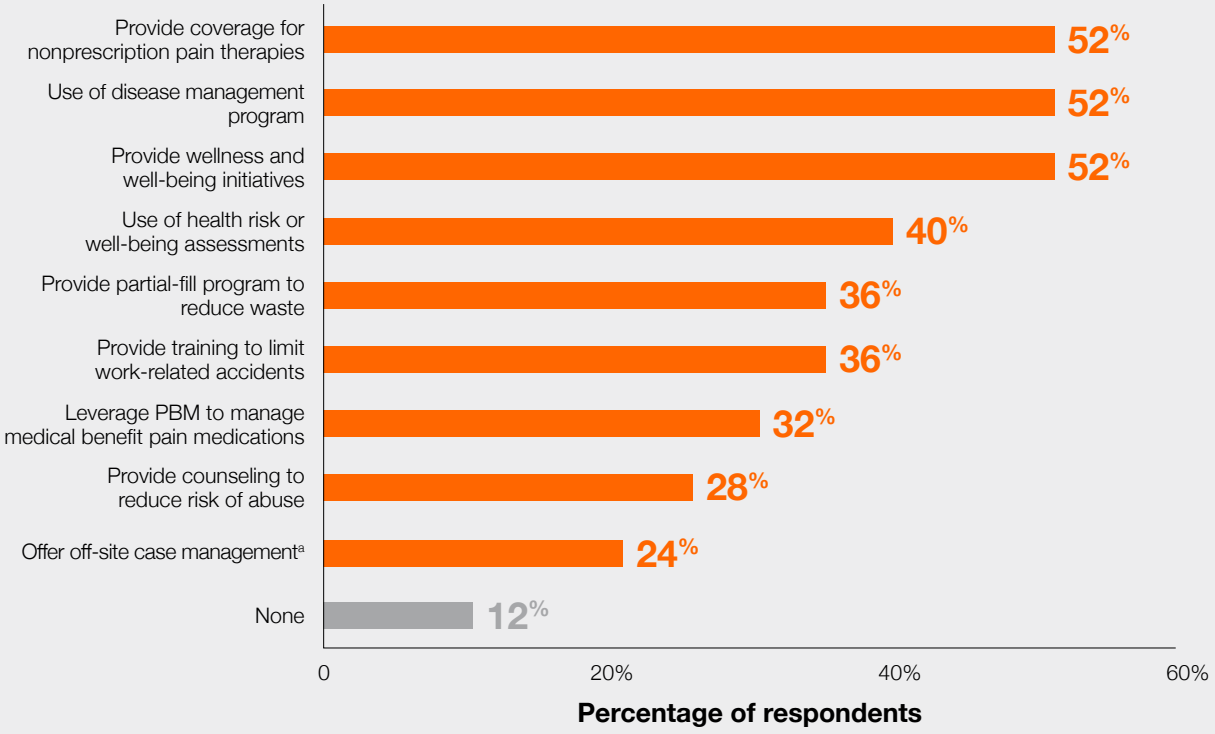
40% Employee benefit consultants

36% Insurance brokers

32% National guidelines

Along with strategic formulary management, employers use different initiatives to address increasing prescription costs, most commonly providing coverage for nonprescription pain therapies, using disease management programs, and providing wellness and well-being initiatives.

Strategies to manage costs of prescription pain medications†



*Which of the following have the greatest influence on your organization's prescription drug coverage decisions? Please select the top 3 influences.

†In addition to formulary status, what are some of the ways your organization is managing costs for prescription pain medications? Please select all that apply.

[a]For employees out on workers' compensation and on pain medication.

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DISEASE MANAGEMENT PROGRAMS

In an attempt to improve the wellness of pain patients and reduce healthcare costs, some employers implement disease management programs. These programs contain different resources and services for patients, such as case management or education on pain management.

52% of employers offer disease management programs for pain.*

Resources most commonly offered by disease management program† (n = 13)

- Case management (69%)
- Education on pain management (69%)
- Nutrition and lifestyle counseling (62%)
- Mobile applications to support participation (54%)
- Hotline for clinical and supportive services (46%)

To encourage the use of a disease management program, **62% of employers** who have a program offer incentives for participation.

Incentives‡ (n = 8)

- Discounts
- Health savings account dollars
- Paid vacations
- Gift cards
- Paid time off for exercise

Employers want to ensure that their program offerings are effective; therefore, they track a variety of metrics relating to program participation and outcomes. Nearly all surveyed employers who use a disease management program for pain are tracking employee participation. However, employers estimate that **only 32% of eligible employees,** on average, actually participate in an offered disease management program.

Metrics tracked§ (n = 13)

- Employee participation (92%)
- Program cost to company (69%)
- Employee satisfaction (69%)
- Medical claims (62%)

The effectiveness of a disease management program is dependent on how success is being measured. Based on employee satisfaction and productivity, 61% of employers indicated that their program is successful. However, when looking from an outcomes or cost management perspective, only 38% of employers reported that their program is successful.

Success of program by perspective[a]‖ (n = 13)

- Employee satisfaction/productivity (61%)
- Pharmacological management (54%)
- Clinical management (46%)
- Outcomes (38%)
- Cost management (38%)

*In addition to formulary status, what are some of the ways your organization is managing costs for prescription pain medications? Please select all that apply.

†Which of the following resources are offered by your disease management program for pain? Please select all that apply.

‡Does your organization offer any incentives to encourage eligible employees and dependents to participate in the disease management program? If so, please explain the types of incentives. [Open-ended.]

§Which of the following metrics are tracked in your disease management program for pain measures? Please select all that apply.

‖Please rate, on a scale of 1 to 7, the success of your disease management program(s) from the following perspectives.

[a]Includes employers who rated the successfulness as a 5, 6, or 7 on a scale of 1 to 7.

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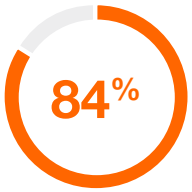
ANTICIPATED CHANGES IN MANAGING THE PAIN CATEGORY



84% of employers anticipate changing their organization's approach to pain management.*

Top anticipated changes in the next 2 years*

44% Improve patient education/communication

40% More generic-only formularies

40% Increase use of copay incentives

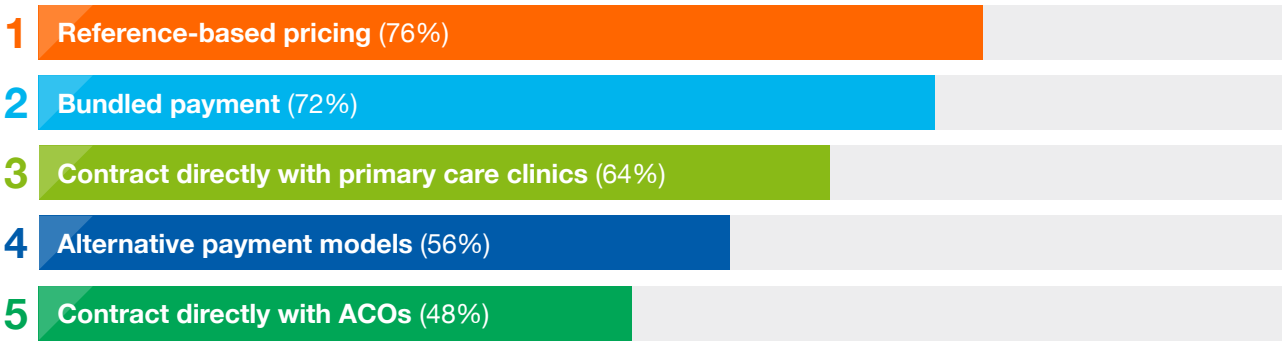
32% Prefer ADFs through formulary management

Changing trends

In the previous survey, the least common anticipated change to pain category management was to improve patient education (32%).

Many employers also anticipate implementing new approaches to contracting for health services. With a continued shift toward value-based care, some employers have already begun contracting with providers directly.

Approaches to contracting for health services[a†]



*Do you anticipate any significant changes to your organization's approach to the management of pain medications in the next 2 years? Please select all that apply.

†Please indicate whether your organization uses or will use the following approaches for contracting for health services.

[a]Currently implemented or likely to be implemented in the next year.

Abbreviation: ACOs, accountable care organizations.

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State legislation to address opioid abuse

Opioid prescribing: Alongside federal efforts to address opioid abuse, individual states will continue to enact their own legislation to encourage responsible prescribing and safe use of opioids. Already, at least 23 states have enacted legislation with some type of limit, guidance, or requirement related to opioid prescribing.[1]

For example, the Strengthen Opioid Misuse Prevention Act, or STOP Act, was signed into law in North Carolina in 2017.[2] This law limits opioid prescriptions to a 5-day maximum supply following a patient's first visit for pain and a 7-day maximum for patients who have had surgery. A larger supply of opioids can be prescribed at follow-up visits, and cancer patients and those receiving treatment for chronic pain are exempt.[2] Along with these duration limits, the STOP Act requires clinicians to prescribe opioids electronically so that they can be aggregated by the North Carolina Controlled Substances Reporting System (NCCSRS), the state's prescription drug monitoring program (PDMP).[2]

PDMPs: PDMPs, such as the NCCSRS, are statewide electronic databases put in place to limit patients' ability to visit multiple prescribers to obtain large quantities of opioids, a practice known as "doctor shopping." By consulting PDMPs, medical professionals making prescribing and dispensing decisions are alerted to other sources from which patients may be receiving drugs.[2] Though PDMPs have been shown to reduce prescription drug–related deaths,[3] they remain underutilized in some states due to their time-consuming nature and difficulties with access and usability.[4]

As a result of these challenges, legislators and healthcare stakeholders will likely increase efforts to enhance access or mandate PDMP use going forward. For example, 39 states have enacted laws that require prescribers to use PDMPs,[5] and it is likely that other states will update legislation to enforce more stringent mandates surrounding PDMP queries rather than just requiring program enrollment. Other efforts to increase prescriber use include the integration of these systems with EHRs and health information exchange systems. This integration can minimize technical challenges and make access to prescribing information more readily available to healthcare professionals.[6] However, it can be difficult to integrate PDMPs into these systems. As a result, some states have started offering grants to facilities that conduct their own integration.[7] Another effort to make PDMPs more effective is the expanded sharing of information across state lines. By sharing data across state lines, state health agencies can help identify doctor shopping and other forms of prescription drug diversion.[8] These types of strategies will help increase use of PDMPs, maximizing their effectiveness and encouraging safe prescribing.

Safe disposal programs for opioids

Take-back programs: Opioid diversion and abuse can occur when patients have pills remaining from their prescriptions. Take-back programs provide individuals with the opportunity to remove excess opioids from their homes, where remaining pills might be diverted or stolen. Public and private organizations have begun implementing programs in accordance with the Controlled Substance Act that allow individuals to turn in unused controlled pharmaceutical substances. These programs provide collection receptacles, supply mail-back packages, and organize take-back events.[9]

Each year, the DEA sponsors nationwide take-back events in the spring and fall. In 2017, it collected over 900 tons of prescription drugs.[9,10] The DEA also encourages communities to partner with local law enforcement to implement additional take-back efforts.[9] Retail pharmacies have also begun to install safe medication disposal receptacles in select stores.[11]

At-home disposal: In January 2018, a major retail pharmacy chain announced its collaboration with a company that manufactures a powder that can be mixed with a medication to convert it into a biodegradable gel. This gel makes the medication's

Abbreviation: EHRs, electronic health records.

Future Trends

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active ingredient difficult to abuse and allows for safe at-home disposal.[11] At all of its pharmacy locations, this retailer now dispenses a packet of the powder with all new Class II opioid prescriptions and has packets available upon request for any existing pharmacy patients.[11] Pending the effectiveness of this program, additional free disposal options may gain traction with other pharmacies in the future.

Value-based contracts for opioids

Payers will continue to evolve their opioid management strategies to address problems associated with abuse and high prescription costs. As more abuse-deterrent formulations (ADFs) come to market, some payers and manufacturers are entering into value-based contracts for these opioid products. The first of these contracts went into effect January 2018 between a large national commercial payer and the manufacturer of an ADF.[12] Based on the contract, the manufacturer will partially refund the payer for the cost of the ADF should the average daily opioid dose exceed a specific threshold.[12] As payers and manufacturers continue to explore these contracts, there will be an increased need for real-world evidence that assesses the ability of ADFs to reduce abuse. Positive real-world data and new forms of contracting could help facilitate access to ADFs in the future.

Alternative pain treatments

As concern about prescription painkiller addiction mounts, professional societies have begun encouraging the use of evidence-based alternative pain treatments. Examples of these therapies include acupuncture, physical therapy, steroid injections, and electrical stimulation. Clinicians are also increasing their use of nonpharmacologic and non-opioid pharmacologic options as first-line therapies to manage pain.[13,14] However, insurance coverage and other financial barriers can stand in the way of patient access to these nonpharmacologic treatments.[15] In an attempt to address this issue, 37 state attorneys general wrote a letter to America's Health Insurance Plans, urging the organization to take proactive steps to encourage its members to review their payment and coverage policies to allow for expanded access to non-opioid and nonpharmacologic pain management options.[16] Given provider preference, mounting scientific evidence, professional guidelines, and a push for coverage from state attorneys general, nonpharmacologic pain management options may begin to receive improved coverage from insurance plans.

Gabapentinoid prescribing for pain

Given the rising concern about opioid abuse, clinicians have begun turning to alternative drug treatments for pain. However, recognizing the potential risks of other treatment options will be important as prescribing patterns change. For example, there has been a significant increase in the number of gabapentin and pregabalin prescriptions written since 2012.[17] Though gabapentinoids are recommended in the CDC guidelines as first-line agents for neuropathic pain, neither an increase in prevalence of neuropathic pain nor an increase in clinician treatment for this condition likely explains the dramatic rise in gabapentinoid use. This trend is attributable, at least in part, to a desire among clinicians to prescribe non-opioid medications to treat a variety of pain types.[17] However, there are several reasons why this trend poses potentially serious concerns.

The evidence that gabapentinoids are effective for off-label uses is not robust, and the side effects of these medications are not trivial.[17] Evidence suggests that some patients—particularly current or past users of opioids and benzodiazepines—misuse, abuse, or divert gabapentinoids.[17,18] More research is needed to clarify the role of gabapentinoids in pain management.[17]

Future Trends

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New classes of pain medications

Neuropathic pain: Researchers are testing the efficacy of various agents in a push to identify new medication classes to treat neuropathic pain. A preclinical study of one such compound demonstrated that it activates sigma-2 receptors, which are expressed in a mix of neuronal and non-neuronal cells thought to play a role in neuropathic pain. This sigma-2 receptor agonist has shown a potency and duration of action superior to that of gabapentin—without producing motor impairment. Though the safety, efficacy, and addictive potential of this agent in humans are still unknown, modulation of this receptor may represent a new way to enhance pain relief while reducing side effects.[19,20]

Other research has shown that a positive feedback pathway called the platelet-activating–factor (PAF) pain loop may exacerbate neuropathic pain.[21,22] In a preclinical study, researchers found that neuropathic pain was attenuated in mice that lacked an enzyme necessary to synthesize PAF.[22] Further research based on this finding showed that pretreatment of cells with a PAF receptor antagonist suppressed PAF production and interrupted the positive feedback loop that sustains neuropathic pain.[22] According to the editor of the journal that published the results, "One has the sense that a new door has been opened to the therapeutics of neuropathic pain."[21]

Abuse potential: Researchers are also currently experimenting with the development of new classes of safe and effective pain medications. A non-opioid agent in development, a monoclonal antibody, received Fast Track designation from the FDA in June 2017.[23,24] This antibody binds to and inhibits nerve growth factor, a protein that shows increased expression in injured or inflamed tissue and is associated with higher levels of pain.[25] Another investigational product is an RNA-mimicking molecule that blocks the series of pain sensitization reactions that normally follow an injury. If approved, this would represent a new class that treats pain without the risk of addiction.[26,27]

Abbreviation: RNA, ribonucleic acid.

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About Daiichi Sankyo, Inc.

Daiichi-Sankyo

As the US subsidiary of a global pharmaceutical innovator, Daiichi Sankyo, Inc., draws on a rich heritage of innovation, integrity, and accountability. While the success of our medicines speaks for itself, our corporate mission defines our vision and purpose: to enrich quality of life around the world through the development of innovative pharmaceuticals.

Established in 2006 by the merger of two 100-year-old Japanese pharmaceutical companies, Daiichi Sankyo, Inc., inherited a rich legacy of innovation and scientific expertise across therapeutic categories. Today, we're just as dedicated to improving quality of life for the patients who need our medicines as our founders were a century ago. Our scientific expertise, robust pipeline, and collaborative and ethical culture make a world of difference in the lives of patients and employees, and in the communities where we live and work.

Commitments in Pain Care

Daiichi Sankyo, Inc., is dedicated to bringing innovative medicines to patients who need relief from their pain. We recognize pain management may require the appropriate use of prescription medicines including controlled substances such as opioids, and that these medicines may be associated with safety concerns such as diversion, misuse, abuse, addiction, or overdose. We are also cognizant of the tragic individual and societal consequences that can result from the improper use of prescription medicines. We are committed to…

- **The well-being and proper treatment of patients** who suffer from pain and to providing prescription medicines to treat their pain and other related conditions
- **Educating healthcare providers, patients, families, and caregivers** on the appropriate use of pain medicines and recognizing and preventing their potential for diversion, misuse, abuse, addiction, and overdose
- **Being a part of the solution** to prescription drug abuse
- **Monitoring prescribing and distribution** patterns for signs of inappropriate prescribing or diversion of these medications
- **Ensuring that our employees are reliable, trustworthy sources** of information about pain treatments, and that our communications about pain medicines will be truthful, accurate, and respect the seriousness of the condition being treated as well as the potential risks associated with these medicines
- **Ethical and socially responsible business practices** at all times, conducting our business fairly, honestly, with integrity, and in accordance with our Standards of Business Conduct

Commitments
IN PAIN CARE

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