

# Opioids and Cancer Pain: Patients' Needs and Access Challenges

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Opioids are a mainstay in the treatment of cancer-related pain and end-of-life symptoms. This class of medications, long used by oncologists, is facing new scrutiny and restrictions as medication and illicit drug abuse in the United States has steadily increased, creating in recent years what has now been termed an “opioid epidemic.” Oncologists experience the opioid epidemic on several fronts: (1) treating patients who have legitimate pain needs in addition to their own addiction issues; (2) seeing patients suffer the repeated heartaches of having a family member struggling with addiction; and (3) now more commonly, facing barriers, restrictions, and hurdles to ensuring that an individual with cancer or cancer treatment-related pain is able to obtain adequate pain control.

The opioid epidemic is real and startling. In 2017, the Centers for Disease Control and Prevention (CDC) reported an estimated 72,000 people in the United States died of drug overdose, with more than 47,000 deaths involving an opioid. The sharpest increase was from the synthetic opioid fentanyl.<sup>1</sup> The escalation of opioid abuse is a complex societal issue and includes contributions from social determinants of health and mental illness. Policymakers and the media often consider a one-size-fits-all solution, which has largely been focused on physician prescribing habits and regulating patient access to opioids.

Cancer pain is also real and startling. It is historically undertreated: eight of 10 patients with advanced cancer experience moderate to severe cancer pain.<sup>2</sup> Approximately 55% of patients with cancer and 40% of survivors experience chronic cancer-related pain.<sup>3</sup> Finally, 43% of patients with cancer and 10% of survivors use opioids to manage chronic cancer pain, with two-thirds of patients with cancer surviving beyond 5 years.<sup>4</sup>

Because of the heightened awareness through the media about the opioid epidemic, patients with cancer are experiencing this fear firsthand, including fear of dying as a result of taking opioids, fear of addiction, and fear of not getting necessary pain medications. A majority of Americans (73%) say new opioid regulations should not apply to patients with cancer.<sup>5</sup>

Recently released results of a meta-analysis of 122 studies addressing pain prevalence and severity in a broad variety of practice locations show that one-third or more patients with cancer and survivors are

having difficulty getting access to their prescribed opioid medications and that the proportion of people experiencing such difficulties has increased markedly since 2016.<sup>3</sup> The vast majority (92%) of US oncology practices are concerned that restrictions on opioid prescribing will result in undertreating cancer pain.<sup>6</sup>

These dynamics make it difficult for prescribing physicians to treat pain, particularly for patients with cancer and cancer survivors. Although judicious prescribing is important, patients with cancer and cancer-related pain need consistent and efficient access to pain control.

## Recent Legislative and Policy Changes

The opioid epidemic will continue to be a bipartisan priority for state and federal governments; more than 100 state bills have been identified. In the upcoming legislative session, there will be state-level consideration of bills related to prescription fill limits, prescription drug monitoring programs review mandates, codification of opioid prescribing guidelines, and overdose medication coprescribing. Bills relative to the identification of outlier prescribers and bills promoting the use of opioid-alternative therapies in cases of acute and chronic pain are also expected. Each of these mandates means new processes as well as complex documentation and education requirements for prescribers.

There are also efforts at the federal level. On July 22, 2016, President Obama signed the first major federal addiction law in 40 years, the Comprehensive Addiction and Recovery Act. The bipartisan legislation authorizes evidence-based prevention, treatment, and recovery programs and law enforcement initiatives to prevent overdose deaths and improper prescriptions. The law allowed for cancer diagnosis exemptions in the pharmacy and provider lock-in programs.

President Trump signed sweeping legislation into law on October 24, 2018, that is touted as the single largest bill to combat the drug crisis in our country's history. It includes provisions aimed at promoting research to find new nonaddictive drugs for pain management. It also expands access to treatment of substance use disorders for Medicaid patients.

On October 26, 2017, President Trump announced that his Administration was declaring the opioid crisis

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a national public health emergency under federal law. As a result, the White House Office of National Drug Control Policy directed numerous federal agencies to address opioid abuse.

Effective January 1, 2019, Medicare instituted new opioid-prescribing policies that will affect Medicare Part D beneficiaries with a prescription drug benefit, and their prescribers.<sup>7</sup> Major changes include (1) real-time safety alerts when a pharmacy dispenses more than a 7-day supply for opioid-naïve patients; (2) a pharmacy alert if the cumulative morphine-milligram-equivalent per day exceeds 90; and (3) several drug management tools to monitor use patterns of frequently abused drugs in patients identified as potentially being at risk. As new opioid safety alerts are implemented in 2019, ongoing communication between pharmacists, Part D plans, and prescribers will be critical. Of important note, residents of long-term care facilities, those in hospice care, patients receiving palliative or end-of-life care, and patients being treated for active cancer-related pain are exempt from these interventions.

### MEDICAL SOCIETY RESPONSE TO OPIOID CHALLENGES IN PATIENTS WITH CANCER

ASCO is sensitive to the need to address the opioid crisis and supports thoughtful and evidence-based interventions aimed at decreasing the prevalence of substance misuse and abuse and overdose deaths. ASCO continues to advocate for appropriate access to pain medications for patients with cancer, recognizing that a “one size fits all” solution risks marginalizing the needs of patients with cancer.

In May 2016, ASCO released a policy statement on opioid therapy that, among other things, emphasized the unique pain management needs of patients with cancer, especially those with advanced disease. In its policy statement and brief, ASCO points out core principles to balance public health concerns and patient needs (Table 1).

In November 2016, the American Medical Association (AMA) House of Delegates overwhelmingly voted to adopt the ASCO-led Resolution: Ensuring Cancer Patient Access to Pain Medication.<sup>10</sup> In short, the resolution stated that the AMA will advocate against arbitrary prescription limits that restrict access to medically necessary pain treatment of patients with cancer.

More recently, in November 2018, the AMA House of Delegates also adopted a late ASCO-backed resolution affirming that some patients can benefit from taking higher doses of opioid pain medication than generally recommended by the CDC and called on the AMA to work with the CDC to provide flexibility in the interpretation of the CDC's opioid prescribing guidelines. The CDC guidelines should only be interpreted as guidance and not misapplied to ultimately limit patient access to these drugs and potentially provoke physician professional discipline.

**TABLE 1.** ASCO Principles for Opioid Access

Principle
Patients with cancer are a special population that should be largely exempt from restrictive regulations intended to restrict access or limit doses.
Providers should have a choice of sources and materials for education in opioid prescribing.
Patients with cancer and survivors of cancer should not be subject to arbitrary prescription limits that artificially limit access to medically necessary treatment.
Patient education on the correct medical use of opioids is best provided by a health care professional with the addition of supplementary materials, as appropriate.
Individual state prescription-drug monitoring programs should be accessible through a single portal or interoperable in a way that is seamless to the user.
ASCO supports efforts to develop abuse-deterrent formulations as one approach to mitigating abuse but notes that most prescription-drug abuse and overdose occur via the oral route.
Individuals with an opioid-related disorder should have rapid access to appropriate assessment, diagnosis, and treatment, regardless of the patient's payer or geographic setting.
Patients should have increased access to naloxone, a lifesaving medication, in cases of opioid overdose by patients, caregivers, and first responders.
To decrease the availability of unused or unwanted opioid drugs, authorized prescription “Take Back” collection sites should be readily available to patients.

NOTE. Adapted from ASCO.<sup>8,9</sup>

### Barriers and Concerns From the Clinic

Oncologists rely heavily on opioid treatment, but we should never rely solely on opioids. Providers of cancer care need to determine if opioids are the right drug for a particular type of cancer-related pain. ASCO published recent clinical practice guidelines for chronic pain management in cancer survivors, careful assessment of the pain and its effect on function, and of the possible risks associated with use of an opioid.<sup>11</sup> Clinicians should screen for pain at each encounter. Recurrent disease, second malignancy, or late-onset treatment effects in any patient who reports new-onset pain should be evaluated, treated, and monitored. Clinicians should determine the need for other health professionals to provide comprehensive pain management care in patients with complex needs. Clinicians may prescribe a trial of opioids in carefully selected patients with cancer who do not respond to more conservative management and who continue to experience distress or functional impairment. Risks and adverse effects of opioids should be assessed. Increased opioid education is being observed, with some states requiring such education for licensure. ASCO has worked closely with the AMA to provide online tools and education programs centered on opioids.

One of the efforts to combat the opioid crisis is restricting the ability of physicians to prescribe opioids. The methods and extent vary by state but include limits on the number of pills

that can be dispensed, requirements to check monitoring programs, and pain contracts. Oncologists have felt this in practice: 40% of practices in the United States have reported having patients who have had trouble filling opioid prescriptions, citing barriers such as prior authorization (69%), pill limits (61%), and caps on maximum doses (44%).<sup>6</sup>

As a result of these regulations, primary care physicians have drastically reduced prescribing opioids and are deferring their patients without cancer to pain specialists. Oncologists continue to be the primary manager of pain for their patients with cancer; however, there are concerns about overzealous prescription monitoring and pharmacy management, fear of legal action on prescribing habits, and frustrations over increased administrative burdens in practices that actively prescribe opioids. Arbitrary restrictions on dosing and pain care provisions must be avoided to ensure patients have realistic access to pain medications.

In conclusion, in our country, millions of patients with cancer and survivors experience acute and chronic pain from many causes. The formidable challenge of the opioid

epidemic has resulted in numerous sweeping, broad-based federal and state government initiatives that risk inadvertently affecting patients with cancer with additional laws and regulations to come.

ASCO supports the public health efforts to reduce the misuse of opioids, yet desires to seek a balance between the government regulation of opioids and the needs of patients with cancer for efficient and compassionate access to pain medications. ASCO stands ready to work with policymakers to ensure any new policies will preserve access to essential pain medications for patients with cancer.

Oncologists realize this is a vulnerable patient population and we will continue to develop and use all the latest advances in comprehensive management of cancer pain in accordance with published evidence-based, physician-developed guidelines. However, we also desire that statutory and regulatory requirements not unduly restrict access to opioids and acknowledge the need to exempt or specifically address cancer-related pain in opioid policies.

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#### **AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST**

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