ORIGINAl RESEARCH

Opioid Utilization Patterns Among Medicare Patients with Diabetic Peripheral Neuropathy

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Background: Diabetic peripheral neuropathy (DPN) affects a large percentage of patients with type 2 diabetes and is associated with moderate-to-severe pain. Patients with DPN bear a substantial economic burden as a result of increased overall healthcare utilization. The reported costs of treating DPN are nearly $11 billion, with elderly (aged ≥65 years) patients with type 2 diabetes accounting for 93.1% ($10.2 billion) of the total costs.

Objectives: To describe the real-world utilization patterns of long-acting opioids (LAOs) and chronic short-acting opioids (SAOs) use in a sample of Medicare enrollees (aged ≥65 years) with painful DPN, and to identify potential areas for improvement in the management of elderly patients with painful DPN who are treated with opioids.

Methods: In this retrospective pharmacy claims analysis, the Chronic Opioid Medication Use Evaluation (MUE) software was used to import and analyze individual plan, retrospective pharmacy utilization claims data from the MarketScan claims databases. Patients aged ≥65 years who had painful DPN as identified by ≥2 International Classification of Diseases, Ninth Revision, Clinical Modification diagnosis codes for painful DPN (250.6X or 357.2) in at least 2 quarters in 2009, and who had ≥1 claims for LAO and/or chronic use of SAO (≥60 days of continuous therapy), were selected for analysis. Pharmacy claim data were extracted for 12 months, and various opioid utilization measures were reported.

Results: A total of 1448 unique Medicare patients with painful DPN were identified who had 11,740 claims for an LAO and/or chronic use of an SAO. Of the 1448 patients, 62% had chronic use of an SAO, and of these, 89% had no concurrent claim for LAO (minimum, 60-day overlap). The most frequently filled LAOs were fentanyl transdermal (38%), oxycodone controlled release (CR; 26%), and morphine CR/extended release (ER)/sustained release (SR; 20%). The daily average consumptions for fentanyl transdermal, oxycodone CR, and morphine CR/ER/SR were 0.3, 2.5, and 2.4, respectively. Among the study population, 15.2% of the patients filled an LAO or SAO prescription at ≥2 pharmacies. Furthermore, these elderly patients with painful DPN used greater doses of LAOs than what is recommended in the package insert, and 1.6% of patients used high doses of acetaminophen and 15.2% utilized multiple pharmacies to obtain their opioid prescriptions. Moreover, this population had prevalent concomitant use of opioids and prescribed gastrointestinal (GI) medications.

Conclusion: Results from our retrospective pharmacy claims analysis demonstrated that elderly patients with painful DPN use doses of LAOs above those recommended in the package insert, with some patients using high doses of acetaminophen and utilizing multiple pharmacies to obtain their opioid prescriptions. In addition, this population had prevalent concomitant use of opioids and prescription GI medications. The use of software, such as the Opioid MUE, to monitor opioid drug utilization trends and examine other utilization measures can assist healthcare decision makers and payers in their utilization reviews to appropriately manage this population.
Diabetic peripheral neuropathy (DPN) is one of the most common complications associated with diabetes, occurring in 30% to 50% of patients with type 2 diabetes and affecting approximately 1 million Americans annually. DPN manifests as spontaneous painful, burning, electric, or shooting sensations in the extremities, with 10% to 20% of patients with DPN experiencing moderate-to-severe pain. Of these patients, 11% to 26% develop chronic pain, which is defined as pain that continues for an extended period of time that may be associated with a recognizable disease process. The American Chronic Pain Association has defined chronic pain as “lasting beyond the usual course of acute illness or injury or more than 3 to 6 months, and which adversely affects the individual’s well-being.” The majority of patients with DPN experience pain on a daily and ongoing basis, which significantly and negatively impacts their quality of life and daily functioning.

Patients with DPN endure a substantial economic burden as a result of increased healthcare utilization (eg, medication use, hospitalizations, and health services visits). The reported costs of treating DPN are nearly $11 billion, with patients with type 2 diabetes comprising 92.5% of the study population and accounting for 93.1% ($10.2 billion) of the total costs. In another study, the total annual direct and indirect costs for patients with painful DPN during the 2006 to 2008 study period ranged from $8435 to $10,120. In contrast, the total costs during this period for diabetic patients without painful DPN ranged from $5536 to $6308. Opioids have been frequently used in the management of painful DPN, particularly as an adjunct treatment for diabetic patients suffering from chronic pain. The various practice guidelines recommend the use of long-acting opioids (LAOs) for continuous pain as part of a multimodal treatment plan if first-line agents that are approved for DPN are inadequate in providing analgesia. However, opioid use in the elderly presents several challenges because of the rapidly increasing population of older Americans, higher incidence of pain, and greater susceptibility to the adverse effects of opioid use.

Opioids are frequently started at doses that are too low for pain relief, and concerns about adverse effects from or addiction to pain medication may further contribute to a high incidence of undertreated pain. The high risks of abuse and misuse related to opioids can also lead to frequent physician office visits and to increased emergency care. Therefore, opioid users must be closely monitored, and dosing adjustments or treatment terminations should be considered when appropriate, to ensure that opioids are administered properly.

Our analysis describes the real-world utilization of LAOs and chronic use of short-acting opioids (SAOs) in a sample of Medicare enrollees (aged ≥65 years) with painful DPN, and identifies areas for potential improvement in the management of elderly patients with painful DPN who are treated with opioids to enhance clinical outcomes and reduce the cost of care for this patient population.

Methods

Study Design and Tool

The Chronic Opioid Medication Use Evaluation (MUE) software (Janssen Pharmaceuticals) was developed to import and to analyze individual health plan retrospective pharmacy utilization claims data to help in assessing chronic use of opioid therapy among plan members. The MUE software provides a cross-sectional perspective of opioid utilization patterns that is based on retrospective pharmacy claims data.

In this current analysis, the Opioid MUE software was used to import and to analyze data from the MarketScan databases. In addition, a reference sample of opioid-treated patients independent of diagnosis was used to com-

KEY POINTS

- Diabetic peripheral neuropathy (DPN) affects 30% to 50% of patients with type 2 diabetes.
- DPN manifests as spontaneous painful, burning, electric, or shooting sensations in the extremities, with 10% to 20% of patients with DPN experiencing moderate-to-severe pain.
- The reported costs of treating DPN are nearly $11 billion, with patients aged ≥65 years accounting for 93.1% of the total costs.
- This study describes the real-world utilization patterns of long-acting opioids (LAOs) and chronic use of short-acting opioids (SAOs) in Medicare enrollees.
- Patients with painful DPN used greater doses of LAOs than indicated in the drug’s package insert, and some patients used multiple pharmacies to fill their prescriptions.
- Furthermore, patients were concomitantly using several opioids and high doses of acetaminophen.
- Approximately 33% of patients with an LAO prescription and 42% of patients with chronic use of an SAO prescription were concomitantly using a prescription gastrointestinal (GI) medication for drug-related GI side effects.
- Medication use evaluation software can help monitor opioid drug utilization trends.
pare study measure results for the study population with painful DPN. The reference group consisted of a 10% random sample of an aggregate IMS LifeLink Health Plan Claims Database from July 2008 to June 2009. The full IMS LifeLink Health Plan Claims Database consists of integrated medical and pharmaceutical claims data from 101 different managed healthcare plans encompassing 65.8 million lives between 1997 and March 2010. In 2008, 37 healthcare plans covering 24.1 million lives contributed to this database. These commercial default reference data provide 1 set of real-world benchmarks based on pharmacy claims between July 1, 2008, and June 30, 2009, for patients who were continuously enrolled in their health plan throughout 2009.

Study Inclusion Criteria

DPN sample. Patients were included in this analysis if they met the following inclusion criteria:

- Aged ≥65 years with DPN as identified by ≥2 International Classification of Diseases, Ninth Revision, Clinical Modification diagnosis codes for DPN (250.6X or 357.2) in at least 2 quarters in 2009
- Had ≥1 claims for LAO and/or chronic use (≥60 days of continuous therapy) of SAO.

Reference sample. A 10% (N = 31,511) random sample of patients from commercial health plans was included in the analysis as our reference population. The patients in the reference sample had ≥1 claims for an LAO and/or chronic use (as evidenced by ≥60 days of continuous therapy) of an SAO. The reference sample did not exclude patients based on age or on DPN status.

The IMS LifeLink Health Plan Claims Database was selected as the data set for the reference sample, because it is nationally representative, including more than 65 million lives and more than 100 health plans. Furthermore, this reference data set was selected for inclusion into the Opioid MUE software to provide a relevant and applicable benchmark for commercial plans when comparing their data.

Where comparisons to the reference group were made, the intent was to provide some context for the descriptive data for the analysis cohort. Although it would have been interesting to define a reference sample that was more similar to the analysis cohort, the reference data set is built into the Opioid MUE software and cannot be manipulated.

Data Source

In this descriptive retrospective analysis, data on patients with painful DPN were obtained from 2 Truven Health Analytics MarketScan Research databases, the Commercial Claims and Encounters Database and the Medicare Supplemental and Coordination of Benefits Database. The MarketScan databases provide service-level claims data for inpatient and outpatient services and for outpatient prescription drugs that are collected from employers, health plans, Medicare, and state Medicaid agencies.

The MarketScan Commercial Claims and Encounters Database contains medical and drug data for more than 45 million individuals who are covered by employer-sponsored private health insurance. Healthcare for these individuals is provided under a variety of health plans, including fee-for-service, fully capitated, and partially capitated health plans.

The MarketScan Medicare Supplemental Database is the first in the United States to provide data on the healthcare experience of retirees with Medicare supplemental insurance paid for by employers. The database provides detailed cost, use, and outcomes data for healthcare services that are performed in the inpatient and the outpatient settings. The database includes the Medicare-covered and employer-paid portions of payment, as well as any out-of-pocket patient expenses. In addition, Medicare beneficiaries in this database have drug coverage, and these drug data offer valuable insight into the drug use and spending patterns of older Americans.

Data Measures

Data were extracted for 12 months from January 1, 2010, to December 31, 2010. The following opioid utilization measures were analyzed: LAO use and the chronic use (ie, evidence of ≥60 days of continuous therapy) of SAOs; the concomitant use of LAOs and the chronic use of SAOs (minimum, 60-day overlap), the most frequently utilized opioids; the average day’s supply; the average daily dose; daily average consumption; opioid rotation (defined as change in therapy within the same formulation group, such as one LAO to another LAO); opioid switching (defined as switching from one opioid molecule and/or formulation to another

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N (%)</th>
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<tr>
<td>Total patients</td>
<td>1448</td>
</tr>
<tr>
<td>Patients with LAO therapy</td>
<td>727 (50)</td>
</tr>
<tr>
<td>Patients with chronic (≥60 days of continuous therapy) use of SAO therapy</td>
<td>902 (62)</td>
</tr>
<tr>
<td>SAO with concomitant LAO claims</td>
<td>97 (11)</td>
</tr>
<tr>
<td>SAO without concomitant LAO claims</td>
<td>805 (59)</td>
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DPN indicates diabetic peripheral neuropathy; LAO, long-acting opioid; SAO, short-acting opioid.
[eg, from chronic use of an SAO to an LAO]; acetaminophen use; unique prescribers and unique pharmacies per patient; the concomitant use of opioids and gastrointestinal (GI) medications, with a minimum overlap of 45 days; and safety and tolerability indicators, including the percentage (1.6%) of patients with evidence of >3.1-g daily acetaminophen use.

Results

The reference group population consisted of 31,511 patients (mean age, 53.5 years). In the elderly painful DPN study population, a total of 1448 unique patients with 11,740 claims for an LAO and/or the chronic use of an SAO were identified (Table 1). The mean age across the overall study sample was 76 years. The chronic use of an SAO was found in 62% of patients; of these, 89% had no concurrent LAO claim (minimum, 60-day overlap; Table 1).

The most frequently filled LAOs were fentanyl transdermal (38%), oxycodone controlled release (CR; 26%), and morphine CR/extended release (ER)/sustained release (SR; 20%), with average day's supplies of 29.2 (reference sample mean, 27.9), 30.0 (reference sample mean, 27.2), and 33.2 (reference sample mean, 28.4) days, respectively. Among patients who were prescribed a new LAO, 45% were started on a fentanyl transdermal patch (reference sample mean, 23%). Oxycodone CR was the most frequently used in combination with a chronic SAO (18%) among LAO users and chronic SAO users.

The daily average consumptions for fentanyl transdermal, oxycodone CR, and morphine CR/ER/SR were 0.3 (reference sample mean, 0.4), 2.5 (reference sample mean, 2.8), and 2.4 (reference sample mean, 2.4), respectively (Figure 1, Table 2). In addition, 5.2% of patients in this sample had an average daily dose between 3.1 g and 4.0 g compared with 3.6% of the patients in the reference sample. For acetaminophen, 1.6% of patients in this sample compared with 0% of the reference sample mean had an average daily dose of ≥4.1 g (Figure 2).

Among the total study population, 24% of patients switched opioid therapy over the study period; opioid rotation (defined as change in therapy within the same formulation group, such as one LAO to another LAO) was observed more frequently in chronic SAO users (20%) than in the LAO users (5%). Approximately 33% of patients with an LAO prescription (reference sample mean, 18%) and 42% of patients with a chronic SAO prescription (reference sample mean, 25%) had evidence
of concomitant use of a prescription GI medication (minimum, 45-day overlap; Figure 3).

Of the patients taking both LAO and SAO medications concomitantly, 20% of LAO users and 23% of chronic SAO users had claims for a prescription GI medication that started with or after the concomitant opioid claim.

Among the population with DPN, 15.2% of the patients filled their LAO or SAO prescription at ≥2 pharmacies. Of these patients, 12.4% filled their LAO or SAO prescription at 2 pharmacies, 1.9% filled their LAO or SAO prescription at 3 pharmacies (Figure 4), and 0.9% had evidence of filling their prescription at ≥4 unique pharmacies.

The majority of elderly patients with DPN use SAOs chronically (62%) without a concurrent LAO (89%). The treatment guidelines for chronic pain recommend that patients start with an SAO and rapidly switch to a CR formulation.

Although the current data used in this study do not provide information on overutilization, health plans can assess utilization and overutilization based on their respective benchmarks.

Discussion

The results of this analysis provide insight into the real-world utilization of LAOs and chronic SAOs in a sample of elderly patients with painful DPN, a population that has not been previously investigated by researchers.

Opioid Utilization

This analysis demonstrates increased opioid use by Medicare patients with painful DPN compared with patients in commercial health plans. Cost implications are also associated with higher opioid utilization patterns, and the excess costs related to painful DPN have been estimated to be nearly $6000 for the calendar year compared with patients without DPN. In the study examining patients with DPN in a managed care setting, the cost difference was largely attributed to an increase in healthcare utilization. The likelihood of any hospital admission for patients with painful DPN was more than 2.5 times higher than that of patients without painful DPN.

Chronic Use of SAOs without LAOs

Results from this retrospective descriptive analysis suggest that the majority of elderly patients with DPN use SAOs chronically (62%) without a concurrent LAO (89%). The treatment guidelines for chronic pain recommend that patients start with an SAO and rapidly switch to a CR formulation. In general, SAOs are considered appropriate for transient pain (eg, acute, breakthrough, or chronic intermittent pain) that does not require long-lasting analgesia. Although LAOs may be associated with...
improved treatment adherence, patients may prefer SAOs because these agents confer analgesic benefit, improve functioning and quality of life, and may have fewer adverse effects.\(^{33}\) As such, treating chronic pain with SAOs or LAOs needs to be customized to the individual patient’s response for the selected treatment regimen.\(^{33}\)

### Daily Average Consumption

The use of SAOs and LAOs for moderate-to-severe chronic pain continues to increase, representing a significant cost for payers.\(^ {34}\) To assess the utilization of SAOs and LAOs, daily average consumptions are frequently used to describe the average number of dosage units dispensed daily based on claims data. Our daily average consumption findings of 2.5 tablets for oxycodone CR are more than the package insert recommendation of every-12-hour dosing.\(^ {35}\) These findings were consistent with previous studies, as well as with those observed in the reference population.\(^ {34,36}\)

In a study by Rubino and colleagues, the unadjusted daily average consumption mean value for the highest strength of oxycodone CR 80 mg was 3.9, and for all strengths was 3.1.\(^ {34}\) Similarly, in a study by Malkin and colleagues, the daily average consumption for all strengths of oxycodone CR was 3.4, with higher strengths associated with daily average consumption values ranging from 2.9 for the 10-mg tablets to 5.2 for the 80-mg tablets.\(^ {37}\)

In another study by Berner and colleagues, the reported daily average consumption value was 3.9 for the oxycodone CR 80-mg tablet.\(^ {38}\) Furthermore, Berner and colleagues calculated the costs for daily average consumption differences for equipotent doses of oxycodone CR and oxymorphone ER using wholesale average costs, and they estimated an average daily additional cost of $10.56 per patient for oxycodone CR 80 mg.\(^ {39}\) Our findings, combined with the findings of these previous studies, suggest the potential for newer and higher dosing options.

### Unique Pharmacies

Most patients in this study utilized 1 pharmacy to fill their opioid prescriptions. However, 12.4\% of patients filled their LAO or SAO prescriptions at ≥2 unique pharmacies. Although this may result from a variety of reasons, the utilization of multiple pharmacies may potentially be associated with opioid misuse. The observation of this behavior warrants further research to more definitively conclude the relationship between a number of unique pharmacies and the potential for and impact of opioid abuse.

### Adverse Effects

Higher doses of opioids are associated with an increased risk of side effects. Specifically, GI adverse effects are common with opioid use, incurring significant costs to patients, as well as negatively affecting function and productivity.\(^ {18,40}\) In a study examining the costs associated with GI events after outpatient SAO treatment, the investigators found that patients with GI event claims had substantially more hospitalizations (adjusted mean, 0.20-0.97 vs 0.17, respectively; \(P < .001\)), hospitalization days (1.12-12.05 vs 1.00; \(P < .001\)), emergency department visits (0.36-1.44 vs 0.25; \(P < .001\)), outpatient office visits (5.68-11.81 vs 4.11; \(P < .001\)), and prescription claims (7.46-8.21 vs 6.06; \(P < .001\)) than patients who did not have any GI claims in the 3 months after the index opioid prescription.\(^ {41}\) In addition, the incremental adjusted mean total healthcare costs for patients with any GI claims ranged from $4880 to $36,152 (\(P < .001\)) compared with patients without any GI claims.\(^ {41}\)

Our study found that 28.4\% of patients with an LAO prescription and 42\% of patients with a chronic SAO prescription took concomitant GI medications after starting opioids. Recent data have suggested that novel opioids with multiple mechanisms of action have similar efficacy with lower GI adverse effects.

Our study found that 28.4\% of patients with an LAO prescription and 42\% of patients with a chronic SAO prescription took concomitant GI medications after starting opioids. Recent data have suggested that novel opioids with multiple mechanisms of action have similar efficacy with lower GI adverse effects.\(^ {41}\) As such, additional research should be conducted to identify all of the conditions and patient populations that would benefit from the use of these new opioids.

### Acetaminophen Use

Although our findings show that a relatively low proportion (1.6\%) of patients use high doses of acetaminophen, nonopioids (eg, acetaminophen) are often the first line of therapy for mild-to-moderate pain because of their relatively safe profile in elderly patients.\(^ {24}\) In our analysis, we only captured prescription acetaminophen and did not account for over-the-counter medication; thus, we are most likely underreporting the problem of acetaminophen use.

Because acetaminophen is used in many combination products, and acetaminophen-related hepatic disease and deaths are found more often in older patients,\(^ {45}\) the treatment guidelines recommend vigilance when pre-
sricption and nonprescription medications containing acetaminophen, because there is a risk of hepatotoxicity with the overuse of acetaminophen.44,45

In particular, with patients who potentially abuse alcohol, it is important to exercise caution in using medications with large amounts of acetaminophen.44,45 Nonetheless, acetaminophen is well tolerated in older patients compared with nonsteroidal anti-inflammatory drugs, which frequently have a worse GI side-effect profile and can be more problematic in older patients.46-49

The use of software, such as the MUE, to monitor drug utilization trends and to examine other utilization measures can assist healthcare decision makers in managing this population and in identifying areas for patient- or physician-directed quality improvement efforts.

Limitations

There are several limitations to this study. First, opioid utilization was based on prescription claims data, which may differ from actual use. As with all claims analysis, there is the potential that prescription claims data used may not be entirely complete, and it is possible that patients may be misclassified and may have missing data. In addition, claims data are primarily used for administrative purposes rather than for research objectives. Therefore, the data may not capture certain clinical characteristics and may not accurately represent treatment diagnostics.

Another limitation is our inclusion of LAOs and SAOs only, which did not encompass all of the available opioids in the United States. However, the vast majority of opioids are included in this analysis, because “a small proportion of use” was our exclusion criterion for opioids. In addition, our study did not account for over-the-counter medications.

Finally, the analysis did not include all of the patients’ diagnoses or account for differences in disease severity because of the lack of data. As such, this analysis only considered patients for whom there were available data, and this may only be representative of a proportion of the elderly patients with DPN.

Conclusion

Pain management and opioid therapy can be complicated in patients with chronic pain, particularly in elderly patients with painful DPN, because of comorbid conditions.50 This retrospective pharmacy claims analysis provides a snapshot of real-world opioid use among elderly patients with painful DPN. Our results demonstrated that these patients frequently use SAOs without LAOs, and they use doses of LAOs that are higher than the dose recommended in the package insert, with a proportion of this population using high doses of acetaminophen and utilizing multiple pharmacies to obtain their opioid prescriptions. In addition, the concomitant use of opioids and prescription GI medications was prevalent in the examined population. The use of software, such as the MUE, to monitor drug utilization trends and to examine other utilization measures can assist healthcare decision makers in managing this population and in identifying areas for patient- or physician-directed quality improvement efforts.

Further research on opioid utilization is needed to better understand the association of the demographic and clinical profiles of elderly patients using opioids for painful DPN. Additional research is also warranted to study the chronic use of an SAO without concomitant LAO use, for higher-than-indicated daily average consumptions for frequently used LAOs, and for the number of prescriptions obtained from multiple pharmacies, to evaluate the association between patient profiles and their opioid utilization pattern. ■

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Author Disclosure Statement

Dr Pesa and Dr Meyer are employees of Janssen Scientific Affairs and stockholders of Johnson & Johnson; Dr Quoc and Ms Rattana are consultants to Janssen; and Dr Mody is an employee of Janssen Scientific Affairs and a stockholder of Johnson & Johnson.

References

Monitoring for aberrant opioid utilization patterns a growing need in managed care

By Curtis Wander, PharmD
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Payers: Appropriate opioid utilization is often a priority to managed care organizations, especially in recent years, as opioid diversion (for recreational use) has increased. With opioid use, there is often a fine line between appropriately controlling pain and overutilizing these medications. Herein lies the challenge for managed care—i.e., the need to set meaningful utilization management into place to allow for adequate pain control for its members while limiting the potential for diversion and overutilization.

In their article on opioid utilization in patients with diabetic peripheral neuropathy, Pesa and colleagues found that within the study population, the average daily consumption of oxycodone controlled release (CR) was

Continued
2.5 tablets. This finding conflicts with the labeled dosing of oxycodone CR, which calls for a once-every-12-hour medication use, especially in the population of patients with diabetic peripheral neuropathy, where the quantities of this medication would not be expected to be as large as in other populations with pain.

Payers also must be vigilant in monitoring aberrant behaviors of health plan members who are utilizing opioids. Trends in utilization that need to be monitored include using multiple pharmacies to fill opioid prescriptions, multiple providers writing opioid prescriptions, and the total number of opioid prescriptions that a member is filling.

Opioid abusers have been found to cost health plans $14,054 more per member than nonopioid abusers in medical and pharmacy costs.1 Utilizing pharmacy limitations to only allow 1 provider to write prescriptions for opioids and 1 pharmacy to dispense opioids for any member showing aberrant behavior should be strongly considered.

**PATIENTS/PROVIDERS:** The management of pain can often be frustrating and challenging for patients. There are several issues that patients need to be aware of while taking opioids.

The potential for tolerance to the dose of the medication, as well as to the opioid, in particular, needs to be communicated. When tolerance to an opioid arises, it can often be discouraging to patients who feel that their pain is becoming worse when an opioid rotation may be necessary.

Opioids are not benign medications, and they carry a host of adverse events, particularly impaired motor function, gastrointestinal (GI) side effects, and respiratory depression. All patients using opioids for the long-term should be aware of the side effects of these medications and should report them to their providers. As noted by Pesa and colleagues, 33% of patients using a long-acting opioid and 42% of patients using a chronic short-acting opioid were receiving concomitant prescriptions for the GI-related side effects.

The proper disposal of opioid medications is very important to the safety of both the patients and the public. According to the US Food and Drug Administration, opioids should be disposed of by either taking them to a Medication Take-Back program or by flushing them down the toilet or sink to keep them away from children and pets.