

Collaborative practice model for management of pain in patients with cancer

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Purpose. The use of a collaborative drug therapy agreement (CDTA) by oncology pharmacists in a comprehensive pain clinic is described.

Summary. Recognizing the complex clinical services required by patients with cancer, the Seattle Cancer Care Alliance began offering cancer pain management through a specialized pain service. Initially, the clinic was staffed by one attending physician; however, as the volume of patient referrals increased, the clinic expanded into an interprofessional team that includes physicians, advanced practice providers, nurses, and pharmacists. Through an extensive credentialing process and under the guidance of a CDTA, pharmacists in the pain clinic are able to evaluate patients, develop treatment plans, and prescribe pain medication therapies for oncology patients. By having pharmacists provide these services, the pain clinic can improve medication dosing, ensure that medications are managed consistently, improve patients' quality of care, and save providers time by allowing tasks to be completed by appropriately trained ancillary staff. For cancer-related pain, the pharmacist, in conjunction with the attending provider, develops a pain medication plan following the principles of the World Health Organization's analgesic ladder. The pain clinic has implemented the routine use of several validated tools for screening and assessment of opioid risk as well as state guidelines for managing chronic opioid therapy. The pharmacists in the pain clinic also emphasize functional goals and improvement in functional status rather than complete relief of pain.

Conclusion. As members of an interprofessional pain clinic team, oncology pharmacists use their specialized knowledge of cancer and pharmacotherapy to help manage and treat pain in complex cancer cases.

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One of the most common symptoms associated with malignancy is pain, which, if inadequately controlled, can adversely affect a patient's quality of life throughout multiple phases of his or her care.^{1,2} A meta-analysis of 52 studies revealed the frequency of cancer-related pain to be approximately 59% in patients receiving cancer treatment, 64% in those with advanced disease, and 33% in patients after curative treatment.³ In addition, there is emerging evidence that survival in patients with cancer is linked to pain management.⁴ Cancer survivors can be affected by pain related to previous treatment modalities,

including surgery, chemotherapy, and radiation.⁵ Therefore, pain management is recognized as a vital part of routine cancer care as well as survivorship and has been advocated by a multitude of professional organizations and institutions, including the Seattle Cancer Care Alliance (SCCA).⁶⁻⁸

This article describes the prescribing authority of oncology pharmacists at the SCCA pain clinic.

Background

SCCA is a nonprofit outpatient cancer center that collaborates with the University of Washington Medical Center (UWMC), Seattle Children's

Hospital, and Fred Hutchinson Cancer Research Center. This alliance allows SCCA to provide advanced therapies, innovative research, and enhanced patient-centered care for patients with cancer in a multidisciplinary setting. SCCA is the only National Cancer Institute–designated comprehensive cancer center in Washington and serves patients from Alaska, Idaho, Montana, Washington, and Wyoming.

Recognizing the complex clinical services required by patients with cancer, SCCA began offering cancer pain management through a specialized pain service. Initially, the clinic was staffed by one attending physician; however, as the volume of patient referrals increased, the clinic expanded into an interprofessional team that includes physicians, advanced practice providers, nurses, and pharmacists.

Pharmacists have been found to improve patient outcomes when they were added to multidisciplinary care teams in hospital and ambulatory care settings, including a variety of specialty clinics, such as anticoagulation, diabetes, hypertension, and pain management.⁹⁻¹² For example, when a pharmacist clinician managed patients with non-cancer-related pain, patients' pain scores decreased significantly after patients' initial visit to a chronic pain clinic (mean $\pm$ S.D. difference in visual analog scale pain score, 1.1 ± 2.6 ; $p < 0.0001$).¹³ Unfortunately, there is limited literature regarding pharmacists' contributions to the management of cancer-related pain.

Oncology pharmacists in ambulatory care clinics are uniquely positioned to provide direct patient education and implement tools that improve medication adherence and medication management.¹⁴ By utilizing collaborative drug therapy agreements (CDTAs), pharmacists can independently order laboratory tests and medications while continuing to provide their regular services, including patient education. In addition, CDTAs standardize prescribing patterns using evidence-based recommendations and improve staff satisfaction.¹⁵

KEY POINTS

- Oncology pharmacists possess specialized knowledge to play a critical role in pain management.
- The pain clinic at SCCA does not have a dedicated FTE pharmacist but utilizes the clinical pharmacists as a shared FTE resource, allowing multiple pharmacists to be involved with the CDTA.
- CDTAs and credentialing allow pharmacists the ability to practice at the top of their license.

The original concept and model for clinical pharmacist participation in the SCCA pain clinic began in the late 1990s, with the integration of a postgraduate year 2 oncology resident. The inclusion of a resident fostered the growth and development of necessary clinical skills in supportive care for oncology patients and provided the framework for future pharmacist responsibilities within the clinic. The resident conducted interviews, developed care plans, and documented patient-related care activities and interventions. In 2002, clinical pharmacists were officially included into the pain clinic's interprofessional team under a CDTA filed with the Washington Board of Pharmacy (now recognized as the Washington State Pharmacy Quality and Assurance Commission). This CDTA enabled pharmacists to provide direct patient care to pain clinic patients and granted permission for pharmacist prescribing activities.

In 1979, Washington became the first state to allow pharmacists to prescribe under a protocol, and the state subsequently enlarged the scope of pharmacists' prescribing authority through a variety of laws and

regulations.¹⁶ In 1991, Washington pharmacists were allowed dependent prescribing authority via CDTAs under any provider licensed within the state authorized to order prescription medications.¹⁷⁻²³

In general, pharmacists planning to exercise prescribing authority via a CDTA must register their protocol or guideline with their state board of pharmacy. Protocols may be submitted from a variety of practice settings including ambulatory care clinics, retail pharmacies, and hospital systems.¹⁸ A single protocol may cover numerous pharmacists working throughout the state. To ensure quality control, CDTAs should be periodically reviewed. In Washington, CDTAs are resubmitted to the board of pharmacy every two years or when new pharmacists are added to the CDTA, whichever comes first.^{18,19}

In response to the rise in opioid abuse, new regulations, such as Washington Engrossed Substitute House Bill (HB) 2876, aimed to implement a system to curb overdose deaths and hospitalizations due to pain medications.²⁴⁻²⁶ This bill replaced existing rules for chronic non-cancer-pain management by implementing dosing guidelines, indications for referral to a pain specialist, requirements for patient outcomes, and conditions for tracking opioid use. A major modification to pain management required the involvement of a pain specialist in the care of patients with chronic pain. In the event that a clinician was to prescribe an opioid daily dose in excess of 120 mg morphine equivalents, consultation with a pain management specialist would be required.²⁴ Patients with acute pain, receiving palliative or hospice care, or with cancer-related pain would be exempt from this consultation process. However, the legislation does not specifically address the management of patients with a history of cancer and chronic pain in cancer survivors. Because of the vagueness of the legislation, many clinicians have conservatively interpreted this complex

population to fall under the category of having chronic pain, thus warranting a referral to a pain specialist. This interpretation has increased the referral of cancer survivors to specialized pain clinics.

Currently, the clinic cares for approximately 250 active oncology and hematology patients as well as cancer survivors. To address the growth at the pain clinic, the care team increased in size, with two attending physicians, one advanced practice provider, three clinical nurses, and seven general oncology clinical pharmacists who conduct rotations within the clinic. Currently, there is no dedicated pain pharmacist full-time equivalent (FTE) at the clinic; rather, each pharmacist, in addition to his or her oncology clinical duties, allots time to see patients at the pain clinic throughout the day.

Privileging and credentialing

In order to execute the pain clinic's CDTA, each pharmacist must obtain a Drug Enforcement Administration (DEA) number to prescribe opioids and then become credentialed. Before initiating the credentialing process, a pharmacist must also obtain a national provider identifier (NPI) through the Department of Health and Human Services. The time to obtain the NPI number can vary.²⁷ To obtain a DEA number, the pharmacist must complete a DEA 224 form and is classified as a midlevel provider; the medical director of the institution serves as the sponsor of the DEA application. The processing time for new DEA applications is approximately four to six weeks.²⁸

A credential serves as documented evidence of a pharmacist's qualifications, which can include diplomas, licenses, and certifications.²⁹ In general, credentialing is a process by which a private organization or government agencies verify and assess a pharmacist's qualifications to provide specific patient care services.²⁹ Although the process at each hospital may differ, credentialing could require submis-

sion of any combination of the following qualifications: education history, pharmacist licensure, NPI number, DEA number, postgraduate training or fellowships, professional work history, board certifications, three professional references, curriculum vitae, faculty appointment, proof of professional liability coverage, and a national certified background check.

After credentialing, the pharmacist is granted privileges to prescribe pharmaceutical agents, order laboratory and diagnostic tests, and document within the medical record. Pharmacists at UWMC/SCCA can expect to be credentialed in three to six months. Pharmacists must have their credentials reappraised every two years. This process includes ongoing monitoring and evaluation for improvement, with three professional references requested to validate the performance of the credentialed pharmacist.

CDTA

Once the pharmacist is established as a credentialed provider, the pain clinic's CDTA guides the pharmacist by outlining the patient population, the responsibilities of the pharmacist, guidelines for medication prescribing, and instructions for pain assessment and management. The overarching goal of the pain clinic's CDTA is to enable clinical pharmacists to provide continuity of care for oncology patients with pain. This goal is accomplished through delineation of the following pharmacist responsibilities: providing adequate and consistent pain management through prescribing authority of opioid analgesics and nonopioid adjunctive therapies, ensuring adherence to the established pain management guidelines, and managing all adverse effects of pain medications.

By having pharmacists provide these services, the pain clinic can improve medication dosing, ensure that medications are managed consistently, improve patients' quality of care, and save providers time by allowing tasks to be completed by appropriately trained ancillary staff.

For cancer-related pain, the pharmacist, in conjunction with the attending provider, develops a pain medication plan following the principles of the World Health Organization (WHO) analgesic ladder.³⁰ The WHO guidelines for direct tumor pain management involve the use of opioids, nonopioids, and adjunct medications.³¹ For patients with chronic non-cancer pain, the pharmacist develops a pain medication plan in accordance with HB 2876 and internal clinic policies.²⁴ Per the CDTA, pharmacists are authorized to prescribe and modify opioid and nonopioid analgesics (e.g., morphine, oxycodone, naproxen), medications to treat neuropathic pain (e.g., gabapentin, venlafaxine) and opioid-induced somnolence (i.e., methylphenidate), and supportive care medications (antiemetics, stool softeners, and laxatives) (appendix). The CDTA agreement also includes additional information on opioid risk assessment, functional assessment, dose adjustment, patient follow-up, adverse effect management, and medication refills.

Clinic workflow

The CDTA outlines the workflow at the SCCA pain clinic (Figure 1). Initial referrals for pain management are received by the pain clinic from oncology providers. These referrals are triaged for appropriateness and order of urgency. Patients meeting the criteria for establishment of care in the pain clinic are scheduled for an initial visit, which usually includes a pharmacist as the primary provider. At SCCA, there are designated clinical pharmacists who act as members of a patient's disease-specific oncology team. Ideally, when a new patient arrives at the pain clinic, the patient is assigned to a disease-specific clinical pharmacist, who can evaluate the patient as an expert in the specific type of cancer. This pharmacist designs a patient-specific pain management regimen and improves the overall continuity of care.

The pharmacist must complete a thorough assessment for each patient.

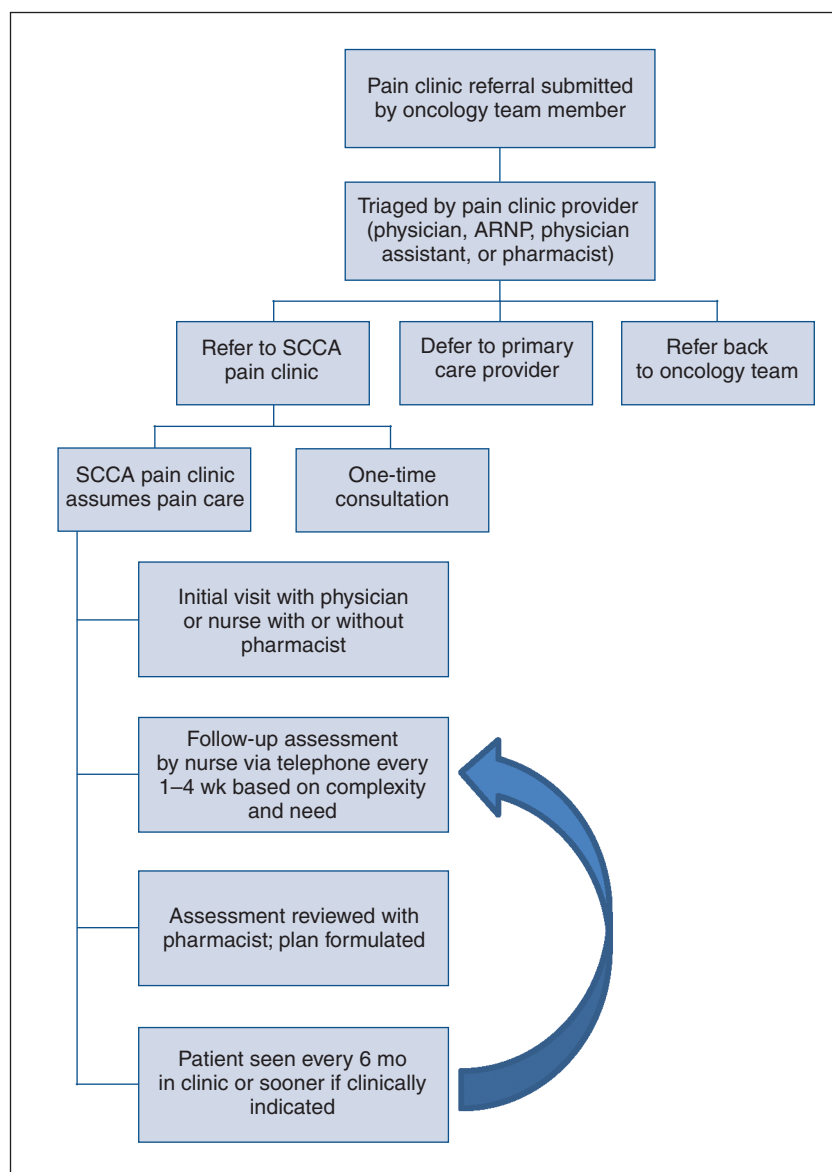
This workup entails a comprehensive review of the patient's medical record to determine the pathophysiology of his or her pain and to review the patient's past and current pain-related medications, cancer treatment, medical history, diagnostic tests, laboratory tests, provider notes, social history, family history, and all of the controlled substances prescribed for the patient in Washington (via the Washington Prescription Monitoring Program [PMP]).

Once the patient has been evaluated, the pharmacist conducts an initial interview with the patient, during which the pharmacist asks the patient about his or her pain, current medication use, and adverse effects of analgesic medications. The patient then completes a variety of screening tools to aid in clinical decision-making, such as the Functional Assessment of Cancer Therapy quality-of-life survey and the Pain Disability Index.^{32,33} The provider uses the information gathered to screen for risk factors for drug abuse or misuse via the Washington PMP, the Opioid Risk Tool, the Screener and Opioid Assessment for Patients With Pain—Revised, and the Current Opioid Misuse Measure (Table 1).^{34–36}

Upon completion of the initial interview, the patient is reviewed with the interprofessional team to determine a formal care plan. After the plan is developed, the attending physician performs a directed physical examination and outlines his or her final impression, including pain complaint, tumor status, and other potential comorbid conditions that contribute to a patient's functional limitations. Functional goals are outlined and reviewed with the patient. The pharmacist then documents this detailed encounter in the medical record.

The patient is instructed to follow up with the clinic at least once monthly for medication refills and evaluation. This follow up is primarily conducted by the nursing staff over the telephone. Afterward, the nurse gives a report to the pharmacist, who reevaluates the patient's clinical sta-

Figure 1. Workflow in the Seattle Cancer Care Alliance (SCCA) pain clinic. ARNP = advanced registered nurse practitioner.



tus, the need for any modification to pain medications or plans, and the need for an in-person evaluation. Per the SCCA pain clinic policy and Washington law, patients are physically evaluated in the clinic at least once every six months or more frequently if clinically indicated.²⁴ The pharmacist may consult with the attending provider to make difficult or complex decisions. All information

and communications are documented in the patient's chart.

Continuous quality improvement

In order to continue delivering the most comprehensive care to patients, various processes and activities have been implemented to help improve the quality of the pain management services provided at SCCA. Some of

Table 1. Validated Tools Utilized in the Seattle Cancer Care Alliance Pain Clinic³²⁻³⁶

Tool	Description	Administration	Length (Estimated Time to Complete)
Functional Assessment of Cancer Therapy (FACT-G)	Assesses function and pain	Patient self-report	27 items (<10 min)
Pain Disability Index (PDI)	Assesses function and pain	Patient self-report	7 items (5 min)
Opioid Risk Tool (ORT)	Screens for risk of opioid addiction	Clinician or patient self-report	5 items (1 min)
Screeners and Opioid Assessment for Patients With Pain—Revised (SOAPP-R)	Screens for risk of opioid addiction	Patient self-report	24 items (<10 min)
Current Opioid Misuse Measure (COMM)	Screens for risk of opioid addiction	Patient self-report	17 items (<10 min)
Prescription Monitoring Program (PMP)	Provides list of all controlled substances prescribed for patient in the state	Electronic database report	Not applicable (1 min)

the activities related to continuous quality improvement include but are not limited to clinic huddles, continuing education, and morbidity and mortality conferences.

Currently, in-person clinic appointments are scheduled twice weekly, on Tuesdays and Thursdays, when attending physicians are present (attending physicians are available for consultations via paging on all other days). The day-to-day clinic operations are the responsibility of the nurses and pharmacists, as the attending providers are offsite on non-clinic days. To improve communication within the team, weekly huddles were implemented. These huddles are an opportunity for nurses, pharmacists, and physicians to gather and discuss challenging patient cases that arise outside of scheduled clinic days. These huddles provide a format for the multidisciplinary team to collaborate and address specific patient care questions and clarify treatment plans to improve overall pain management. Monthly pain team meetings are also held as a forum to discuss upcoming changes to staffing, clinic logistics, updates on new drugs or guidelines, and general questions or concerns.

As guidelines and strategies for pain management are revised frequently, the institution recognized

the vital importance of providing opportunities for continuing education. To accomplish this, the pain clinic developed a series of didactic sessions for the residents, fellows, nurses, and pharmacists. Ten lectures are conducted every year and presented weekly from September through November; they are taught by pharmacists and physicians. Topics include Washington law, the Washington PMP, the WHO analgesic ladder, tools for opioid risk assessment, interpretation of laboratory test values, and neuropathic pain. This didactic series reviews in detail the appropriate dosing of opioids, methods for pain assessment, and adjunctive medications used in pain management. In addition, the series provides helpful tools and strategies to conduct a comprehensive pain workup of patients. These versatile lectures give staff a thorough and standardized approach for managing patients' pain, allowing personnel to deliver effective and comprehensive pain management.

Finally, pharmacists have the opportunity to participate, learn, and reflect by attending morbidity and mortality conferences that occur several times a year at SCCA. This is a forum where difficult pain and oncology patient cases are discussed, with the goal

of improving overall outcomes in the future.

Outcome measurements are necessary to evaluate the effectiveness of the pain clinic. Although no formal outcome measures for internal continuous quality improvement have been exercised routinely, resident research projects have served as a platform to assess clinic performance. Past resident research has included assessment of electrocardiogram monitoring for patients on methadone and evaluation of the clinic's urine toxicology screening protocol. These resident projects have helped shape the internal practices of the clinic. SCCA is currently evaluating the use of resources within the pain clinic as the service continues to expand. Results from this internal survey may aid with reallocation of current resources or provide evidence needed to obtain additional resources.

Overcoming barriers to success

As with any practice model, the SCCA interprofessional pain clinic team has encountered challenges, as the clinic has expanded in size and scope of the patients managed. Continuity of care is a strength of the CDTA; however, with the current pharmacist staffing model, it is also an area

of ongoing improvement. All clinical pharmacists must staff both clinical and drug distribution services. In this staffing model, all of the clinical pharmacists participate in managing pain clinic patients as part of their daily activities during their rotation on clinical service. To address issues of continuity, the weekly huddle allows pharmacists whose next rotation is on the clinical service the opportunity to stay updated on pain management plans. Furthermore, when pharmacists change services, all pertinent patient care activities are relayed to the pharmacist moving onto that clinical service via handoffs, either orally or through e-mail.

Another challenge is resource utilization as it relates to the amount of time that pharmacists spend completing pain clinic activities versus other job functions due to the nature of shared FTEs. An internal review of pharmacists' time revealed an average of 3 hours spent with each patient per pharmacist, which included a workup, clinic visit, and documentation. With approximately seven pharmacists seeing one patient per week, the total pharmacist hours dedicated to clinic visits is at least 20 hours per week. Additional pharmacist time is spent consulting with nurses to help triage patient care issues, prescribing refills, and reviewing pertinent laboratory test results. Although these time data have not been formally captured, it is estimated to take an additional 20–30 hours per week. To help alleviate the burden, pharmacists' schedules for chemotherapy teaching are blocked off during pain clinic days to avoid overlap. Due to the shared nature of clinic visits with an attending provider, the pharmacist does not bill separately for his or her hours.

A final challenge that accompanies the pain clinic's CDTA is the provision of care for out-of-state patients. Since SCCA is one of the only comprehensive cancer centers in the Pacific Northwest, the institution frequently encounters patients residing in the surrounding states. Under the pain

clinic's CDTA, pharmacists are not authorized to prescribe medication for patients from out of state due to legal constraints and other boards of pharmacy not recognizing pharmacists as providers. In these cases, the pharmacist performs the patient workup and clinic interview, but the attending physician ultimately must prescribe for these patients.

In addition to the challenges within the pain clinic practice model itself, there are specific barriers to managing cancer-related pain and chronic pain. In 2013, the National Survey on Drug Use and Health revealed that 15.3 million people age 12 years or older had used prescription drugs for nonmedical purposes over the past year; of those, 6.5 million had used a prescription drug within the past month.³⁷ These statistics, combined with provider perception of the increased risk related to opioid misuse and addiction, may lead to reluctance in prescribing or escalating opioid therapy. Moreover, numerous national and state regulatory agencies, such as the Agency Medical Directors' Group in Washington, have developed guidelines and regulations regarding the prescribing of opioids that may complicate access to medications.³⁸ Prescribers may also face concerns about liability when issuing opioid prescriptions, particularly with the higher doses often associated with the treatment of cancer pain. Lastly, the ongoing monitoring of patients receiving opioid therapy can be a daunting task, with the need for continuous assessment of adherence, tolerability, and effectiveness.

To address these issues associated with opioid prescribing and monitoring, the SCCA pain clinic has implemented the routine use of several validated tools for screening and assessment of opioid risk as well as state guidelines for managing chronic opioid therapy (Table 1).³⁸ The pharmacists in the pain clinic also emphasize functional goals and improvement in functional status rather than complete relief of pain. Taken together, these

tools and measurable functional goals serve as an objective way for pharmacists to monitor and assess patient progress, especially for patients with complex chronic treatment-related pain and cancer survivors. Functional goals have also been quantified, using referrals to physical therapy and psychotherapy as part of the treatment plan.

As the number of providers and patients in the clinic expands, the role of the pharmacist continues to adapt to meet the increased demands while delivering effective patient care. Although no formal examination of the pharmacists' perceived value has been conducted, SCCA is currently conducting an internal review of patient demographics and staff time commitments. The optimal goal is to use these data to best allocate resources and staff.

Conclusion

As members of an interprofessional pain clinic team, oncology pharmacists use their specialized knowledge of cancer and pharmacotherapy to help manage and treat pain in complex cancer cases.

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Appendix—Authorized pharmacist prescription medications under the Seattle Cancer Care Alliance pain clinic collaborative drug therapy agreement^a

Antibiotics

Amoxicillin
Levofloxacin

Benzodiazepines

Clonazepam
Diazepam
Lorazepam

Central nervous system stimulants

Methylphenidate
Modafinil

Nonopioid analgesics

Acetaminophen
Anticonvulsants
Gabapentin
Pregabalin

Nonsteroidal antiinflammatory drugs

Ibuprofen
Naproxen

Opioid analgesics

Codeine
Fentanyl
Hydrocodone
Hydromorphone
Methadone
Morphine
Oxycodone
Oxymorphone
Tramadol

Supportive care medications

Antiemetics
Metoclopramide
Ondansetron
Prochlorperazine
Antihistamines
Diphenhydramine
Hydroxyzine
Medications used to treat constipation
Docusate
Polyethylene glycol
Senna

Tricyclic antidepressants

Amitriptyline
Nortriptyline

^aThis is not a comprehensive list of all medications prescribed, rather those most commonly prescribed in each class.