ONCOLYTICS TODAY

EMPOWERING THE MEDICALLY INTEGRATED ONCOLOGY PHARMACY PRACTICE | FALL 2019

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How it works:

Cost Avoidance: Whenever you perform an intervention for a patient that helps prevent an unnecessary Rx from being given to a patient, *record the savings.*

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To learn more about the tracker tool, please visit www.ncoda.org/CAWT

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NCODA's focus is to advance the value of dispensing practices for oncology physicians. We will provide leadership, expertise, quality standards and sharing of best practices with all members. We will deliver positive outcomes through collaboration with all stakeholders involved in the care of oncology patients.

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NCODA HAS PUT A WHOLE NEW SPIN ON THE CONCEPT OF CHANGE

There are mountains of papers and articles written about "change" – how to handle change, the positive effects of embracing change, yada, yada, yada.

Change, for many people, can be an unpleasant word signifying the onset of more work.

But looking back at the work we have accomplished through NCODA in its first five years, especially in the last two years, our organization has put a whole new spin on the word.

James Schwartz

Who knew change could be so **exciting, invigorating, welcome!**

At the time NCODA was formed, the oral oncology component of cancer care was a bleak, desolate wasteland – multiple cancer practices scattered all over the country, each developing their own standards, protocols, patient education materials, etc.

NCODA was founded to address the growing need for dispensing cancer clinics to improve operations at the pharmacy level, as well as the need to deliver quality and sustainable value to all stakeholders involved in the care of cancer patients receiving oral therapy.

NCODA brings value to practices through adoption of quality standards, sharing of best practices and improvement of financial viability.

The changes we (physicians, nurses, APPs, pharmacists, technicians, administrators, pharmaceutical partners and institutions) made have dramatically improved outcomes for oral chemotherapy patients.

These changes, in turn, accentuate the positive effect of the changes necessary to improve healthcare and the adoption of the many innovations being introduced.

The NCODA board of directors empowered the staff to make this organization the go-to resource for all oral oncology information/practice.

NCODA is collaborating with the American Society of Clinical Oncology (ASCO) to develop Oral Oncology Dispensing Standards for enhancing the Quality Oncology Practice Initiative (QOPI) program.

The Oral Chemotherapy Education (OCE) sheets are completely up to date, with all newly released drugs included.

The success of these education tools has stimulated many practices to request that NCODA develop the same concise, accurate, easy-to-read documents for all injectable chemotherapy agents.

We are in discussion with our partners at the Oncology Nursing Society (ONS), Hematology Oncology Pharmacy Association (HOPA) and the Association of Community Cancer Centers (ACCC) to develop a process for creating IV Chemotherapy Education sheets as well.

This August, we hosted the first (and hopefully an annual) Oncology Institute to provide information on the many aspects of oncology care and the role drug utilization plays.

This event was provided by (and with input from) our pharmaceutical partners to assist them and healthcare providers in gaining a better understanding of the issues oncology practices face.

The Positive Quality Intervention (PQI) documents developed by NCODA members are a standard of care in many practices. We received several documented testimonies in 2018 and 2019 regarding their relevance and value.

Two valuable NCODA subgroups – the Nursing Committee led by Mary Anderson and Elizabeth Bettencourt, and the Oncology Pharmacy Technician Association (OPTA) led by Linda Grimsley and Sarah Stadt – have been formed and are lending their expertise to the various NCODA programs.

Also, NCODA Professional Student Organization chapters have been initiated at several pharmacy schools throughout the country.

Our 2019 Spring Forum in Denver was another great meeting, where 265 clinicians and more than 400 participants gathered to discuss the important topics related to oral oncolytics. The 2019 Fall Summit will be held Oct. 24-26 in Orlando, Florida.

Finally, on behalf of NCODA and its membership, I want to thank all of our sponsors (pharmaceutical companies, educational institutions, professional organizations), as well as the NCODA staff for making such a valuable contribution to our Mission.

Together we are making a big, big difference!

James R Schwartz

James R. Schwartz, RPh
NCODA President, 2019-2020

MEDICALLY INTEGRATED PHARMACIES:

RISING TO THE CHALLENGE

By Claudia S. Castro, PharmD, MS, BCOP, BCGP

The direct medical costs of oncology care in the U.S. was estimated by the Agency for Healthcare Research and Quality (AHRQ) in 2015 to be $80.2 billion.[1]

Much like the entire healthcare system, the high cost of oncology care is not an indicator of the quality of care received; so much so that the Institute of Medicine (IOM) published the report "Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis."[2]

Claudia S. Castro

Much of the high cost of oncology care is attributed to the rise in oral oncolytics available in today's market. Consequently, Medically Integrated Pharmacies (MIPs) have risen from the need to provide high-quality pharmacy services while reducing costs to both patients and the healthcare system.

In its report, the IOM provides a framework for what it deems necessary to improve the quality of oncology care and to move oncology care out of the crisis.

The following is an outline of the framework, as well as a discussion of how MIPs rise to the challenge.

IOM'S CONCEPTUAL FRAMEWORK[2]

Engaged patients: It is largely known that patient adherence to therapy is a critical factor in achieving optimal outcomes and can have a detrimental effect on the quality of oncology care provided. Patients must feel empowered and engaged in their healthcare. Pharmacy staff in MIPs work to provide patient-centered care, a critical factor in improving the quality of oncology care.[3]

Pharmacists provide patient education on drug administration, handling, and side effect management. They ensure patients receive the ancillary medications that are commonly required with oral oncolytics, such as anti-diarrheals and anti-emetics.

Pharmacists ensure that patients are aware of what to expect from their oral oncolytic therapy and even discuss the information with family members and friends as appropriate and necessary.

Pharmacists are supplemented by highly trained pharmacy technicians who play key roles in addressing patient financial concerns and call patients on a routine basis to fill their medications at the appropriate times.

The pharmacy technicians ensure patients have access to their medications at the right time and the right place. They take into account such factors as drug holidays, surgery and radiation schedules. They even schedule drugs to be delivered to alternate U.S. locations where a patient may be vacationing or visiting.

An adequately staffed, trained and coordinated workforce: MIPs employ highly trained pharmacists who specialize in oncology and are routinely board-certified.

It is commonly noted that the U.S. healthcare system suffers from fragmentation, a key factor in high cost and less-than-optimal quality.

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Each and every member of the oncology patient's healthcare team must prioritize the need to improve the quality of oncology care delivery, while reducing costs. There is no role too big or too small. Together, we can overcome this crisis; our patients deserve it.

CHALLENGE

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Staff in the MIPs work directly with the clinic staff and are members of the patient's healthcare team. They assist in providing comprehensive oncology care and in improving care coordination.

Evidence-based cancer care: Pharmacists in MIPs frequently refer to National Cancer Institute (NCI) and American Society of Clinical Oncology (ASCO) guidelines when providing recommendations to providers, nurses and patients.

FDA approvals and drug labels lag behind the science regarding what drives specific cancers, particularly molecular targets and genomics behind the disease.

Because of this, pharmacists leverage their close relationships with oncologists to stay abreast of the latest case reports, data and studies to help ensure patients are receiving real-time, evidence-based cancer care.

Pharmacists utilize this information when processing orders, counseling patients and writing appeals in response to insurer denials of payment for oncolytics.

A learning healthcare information technology (IT) system for cancer: The Centers of Medicare and Medicaid Services (CMS) has developed the "Promoting Interoperability Programs" to provide incentive payments for the implementation of electronic health records (EHRs). Healthcare experts nationwide and CMS view EHRs as a key component in the efforts to improve the "quality, safety, and efficiency of patient healthcare."[4]

As part of the healthcare team, MIPs have shared access to the patient's EHR and regularly communicate and document in the EHR.

In some cases, the MIP's creation has led to the implementation of e-prescribing, moving clinics out of the age-old habit of printing, manually signing and faxing prescriptions to pharmacies.

In addition to a shared EHR, many MIPs also utilize a patient management system, such as Dromos or Mediware. These systems provide the tools necessary for monitoring patient progress such as outcomes and adherence. Also, they provide a means to track and easily report key metrics required by pharmacy stakeholders, such as accrediting bodies, insurance companies and pharmaceutical companies.[5,6]

Translation of evidence into clinical practice, quality measurement and performance improvement: Many MIPs accomplished the vigorous task of receiving accreditation from such organizations as the Utilization Review Accreditation Committee (URAC) and the Accreditation Commission for Healthcare (ACHC).

These accrediting bodies set standards in an effort to improve quality and outcomes, while fighting against rising costs. MIPs must demonstrate that they meet these standards and participate in an on-site survey process prior to receiving accreditation.

Accredited pharmacies must repeat the survey process every three years and demonstrate continued compliance with the quality standards set forth by the accrediting bodies.

Accredited pharmacies also must submit their measurement data to the accrediting

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CHALLENGE

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body each year. Measurement data includes such factors as turn-around time for each prescription filled and patient satisfaction.[7,8]

URAC reports that its accredited pharmacies have exceeded reported measures in 2018 as compared to 2017.[7]

Accessible, affordable cancer care: The advancements in oncology medications, particularly oral oncolytics, are both a blessing and a curse.

For example, the out-of-pocket cost of one month of an oral oncolytic can cost upwards of $20,000 per month, with much of that cost passed on to patients in the form of copayments and deductibles. This has led experts to attribute an additional toxicity to cancer treatment termed "financial toxicity."[9]

One of the MIPs' top priorities is to reduce the financial toxicity associated with obtaining treatment with oncolytics. Highly-trained staff work with patients to obtain copay cards from drug manufacturer websites to either reduce or eliminate patient copayments.

They also assist patients in navigating the complicated process of gathering financial documents and completing the paperwork required to enroll in patient assistance programs in order to obtain free drugs from drug manufacturer websites (for those that meet specific guidelines).

Lastly, they also search for grants on a regular basis, assisting patients in covering much, if not all, of the out-of-pocket costs.

MIPs also playing a valuable role in eliminating waste in the healthcare system.

The ability of MIPs to access the patient's electronic medical record and communicate with providers and clinic staff prevents the delivery of medications when a patient's dosage is reduced or the drug discontinued.

Summary: As the population ages and cancer survivors live longer due to advancements in cancer therapies, the cost of cancer care will continue to rise.

Each and every member of the oncology patient's healthcare team must prioritize the need to improve the quality of oncology care delivery, while reducing costs. There is no role too big or too small. Together, we can overcome this crisis; our patients deserve it.

▲ **Claudia S. Castro**, PharmD, MS, BCOP, BCGP, is a Clinical Pharmacist Specialist at Partners HealthCare Specialty Pharmacy in Massachusetts. She is also a member of the NCODA Editorial Board.

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NCODA's Quality Standards are instrumental for the successful implementation and maintenance of Medically Integrated Pharmacies. These Quality Standards were created to elevate the performance of oncology practices. Aligning around these Standards allows practices to optimize compliance and efficacious therapy. For more information, visit **www.ncoda.org** and search "Quality Standards."

PATIENT ACCESS IS ESSENTIAL IN ADMINISTERING ORAL ONCOLYTICS

By Carol Hemersbach, CPhT, BSHCA

Cancer is a diagnosis no patient wants to hear; the word alone can devastate families emotionally, physically and financially.

In the past, most chemotherapy has been in the form of intravenous therapy, given either in the hospital setting or at an outpatient infusion center.

The past few years have produced numerous new oral chemotherapy agents that can be taken by the patient in the comfort of their own home, without the need to drive to the hospital or oncology office to spend hours in an infusion chair.[1]

Unfortunately, the cost of these oral drugs can be astronomical, directions on how to take them can be confusing, prior authorizations are usually required and patient adherence is often a problem.

Because of the excessive cost of these oral cancer medications, many patients are unable to afford their copay and opt out of taking their prescriptions. This creates a barrier for patients because of the hindered access to the medication.[2]

The reality is that many Medicare patients live on Social Security. Medicare rules make it difficult to find assistance, while payers are creating stricter criteria and increasing patient responsibility for both Medicare and commercial insurance.

In 2013, IMS, the largest vendor of prescribing data in the U.S., revealed that 29.9% of retail out-of-pocket (OOP) costs were due to specialty drugs. Yet these drugs only account for 2.3% of prescriptions.[3]

SOLUTIONS AVAILABLE

There are solutions to this dilemma, but it requires knowledge on available assistance for copays, various free drug programs and insurance issues.

Prior authorizations are required from payers for the majority of cancer drugs. While turn-around time for obtaining prior authorizations was not excessive, delays related to the actual procurement of the medication were significant.[4]

A recently published study revealed that out of 324 prescriptions requiring prior authorizations, 97.5% were approved even though they were prescribed within the standard of care.[4]

Medication adherence is a significant barrier in healthcare. According to the National Association of Chain Drug Stores, for every 100 prescriptions written in 2011, 50-70 were filled at a pharmacy, 48-66 were picked up from a pharmacy, 25-30 were taken as prescribed and only 15-20 were refilled as prescribed.[5]

In a study, implementation of a pharmacy within the oncology facility led to a higher capture rate of new prescriptions, with an average adherence rate of 89%, and improved patient knowledge of their chemotherapy regimen.[6]

Adherence is more than just taking medications. It can include not taking medications as prescribed as well as self-discontinuation.

MEDICALLY INTEGRATED ALTERNATIVE

One proposed solution would be to have a medically integrated pharmacy, whether in a hospital or in-office setting, with experienced staff to review these prescriptions.

Initiating a pharmacy-led management program in which a newly prescribed oral oncolytic can be reviewed prior to beginning the process of obtaining the drug will reduce errors, as well as promote patient safety, education, monitoring and follow-up.

It has been demonstrated that because of the increasing complexity of oncology drug regimens, there is an increase in the potential for error. The utilization of educational materials and interactions with patients will aid in

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OCE SHEETS: STANDARDIZED, APPROPRIATE, AVAILABLE

By Tyler Redelico, PharmD, BCOP

For a healthcare practitioner in oncology, it's tough to stay up to date with the latest information. In 2018, the FDA approved 59 novel drugs – 17 of which were oncolytics and all but six were oral.[1]

Oral oncolytics have unique challenges: patients must remain compliant, minimize hazardous exposure and may have less contact with their healthcare team compared to someone receiving parenteral medications.[2]

I am proud to be a part of the Oral Chemotherapy Education (OCE) effort through NCODA with ACCC, HOPA and ONS to help optimize patient education of oral oncolytic medications.

Since affiliating with our parent site five years ago, my hospital has maintained its own patient education database for oncolytics. Many of our handouts were based on those from MD Anderson Cancer Center. Most recently, some had to be developed from scratch.

For oral oncolytics, we transitioned to OCE sheets for a multitude of reasons:

- They are standardized documents that are maintained and well-written.
- They are readily available online.
- They contain appropriate information for patient-centered interaction.

The decision to utilitze OCE sheets saved my hospital hours of research work per drug while providing our patients a superior resource.

Each sheet lists common adverse effects alongside symptoms and management tips. By focusing on adverse effects that occur more commonly in patients, as well as noteworthy warnings and precautions, the sheets consistently detail the most pertinent toxicities.

OCE sheets are the gold standard in oral oncolytic patient education.

Each handout also addresses challenges with oral oncolytics such as administration, storage and safe handling.

All 11 oral oncolytics approved in 2018 have a patient handout at oralchemoedsheets.com, and those approved in 2019 will be created as they arrive.

The OCE sheets are reviewed and maintained on a quarterly basis along with any significant clinical updates.

OCE sheets are the gold standard in oral oncolytic patient education. For information, visit **oralchemoedsheets.com**.

▲ **Tyler Redelico**, PharmD, BCOP, is the outpatient clinical pharmacist at MD Anderson Cancer Center at Cooper in Camden, New Jersey.

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PATIENT ACCESS

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decreasing patient risks for errors.[7]

Staff can follow up on the process and status daily to ensure timely initiation of therapy. The team can search for assistance for the drug. And before the prescription is filled and dispensed to the patient, a pharmacist can review the medication with the patient, providing education needed to ensure proper adherence.

Research has shown that patient access to oral oncology medications is a real problem, creating a barrier in healthcare. This barrier exists because of numerous reasons including cost, accessibility from the manufacturer,[3] patient education, adherence, and insurance control over specialty medications.[4]

With knowledgeable and caring staff, creating easy access to oral oncolytics can allow patients to concentrate on their disease and eliminate worry about how they will afford these medications.

▲ **Carol Hemersbach**, CPhT, BSHCA, is an admixture/IOD technician at Arizona Blood & Cancer Specialists.

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OPTA

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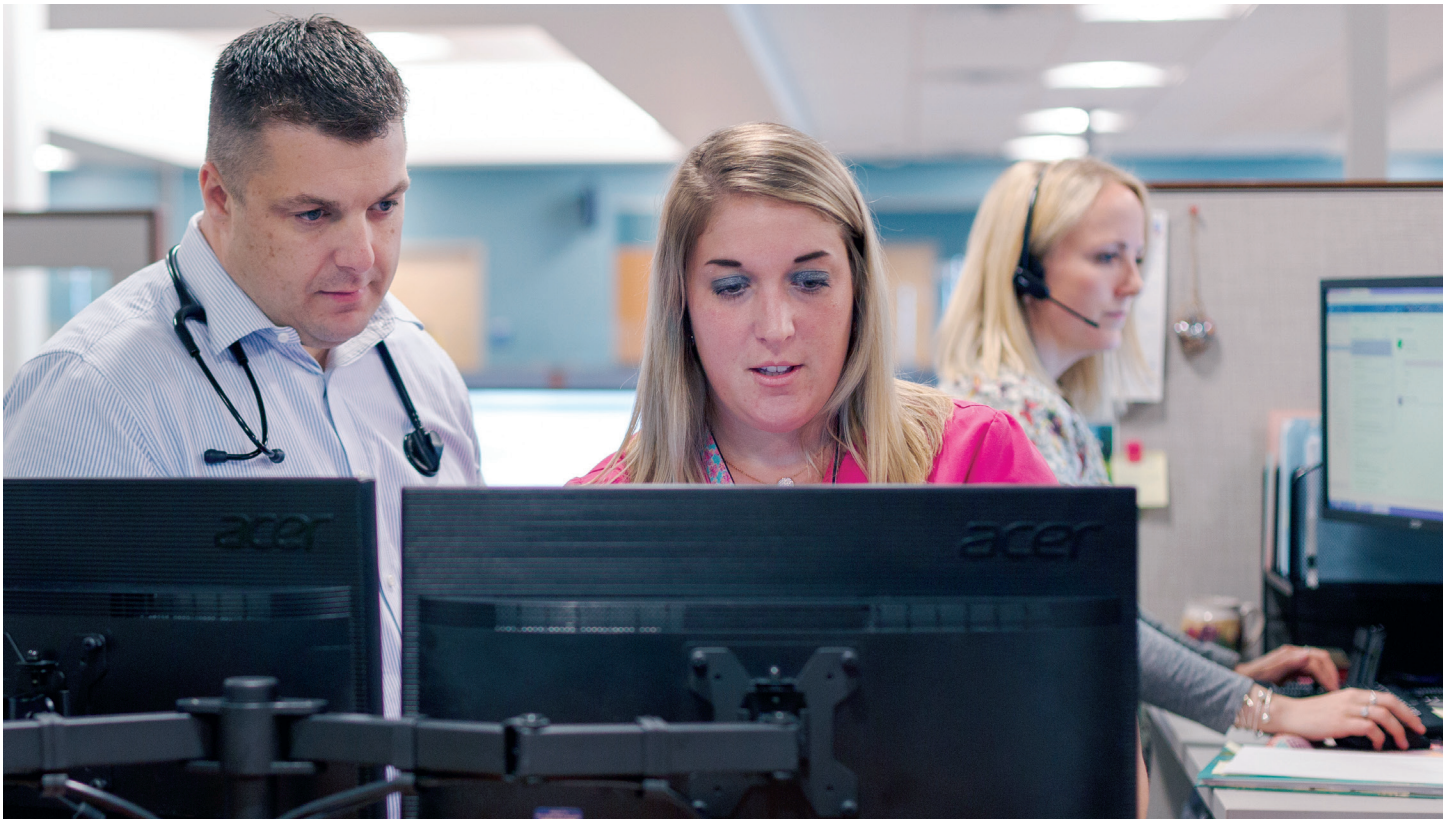


OPTA – the Oncology Pharmacy Technician Association – is the first professional association dedicated to supporting and encouraging the professional development of oncology pharmacy technicians

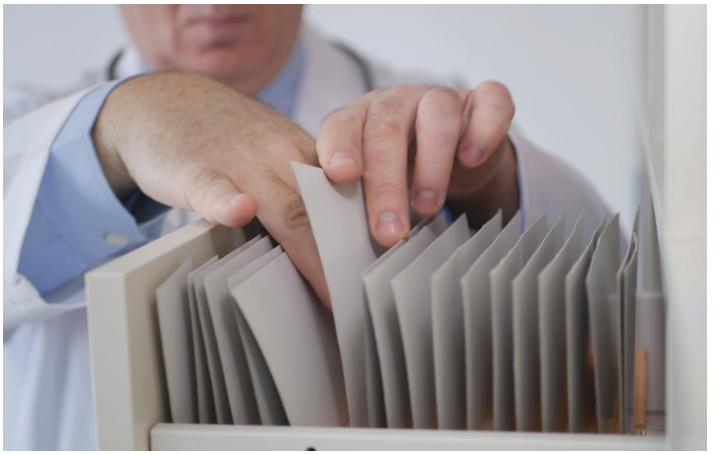
OPTA strives to strengthen and empower dispensing staff's vital role by providing leadership and sharing knowledge to ensure better patient outcomes.

OPTA connects members from across the nation.

OPTA helps set the standards for oncology pharmacy technicians.

OPTA's success is dependent on the contribution of each individual member. Join us and let your voice be heard to help improve patient care!

FOR MORE INFORMATION OR TO SIGN UP FOR COMPLIMENTARY OPTA MEMBERSHIP, VISIT:
www.ncoda.org/oncology-pharmacy-technician-association-opta



CREDENTIALING AND ACCREDITATION FOR THE MEDICALLY INTEGRATED PHARMACY

By Michael Brodersen, PharmD

Medically integrated dispensing within community oncology centers has proven to be effective, if not optimal, in the overall management of oral oncolytic therapies.[1]

Medically integrated pharmacies (MIPs) are in an ideal position within the clinic to provide patients with their much-needed cancer treatment in a timely and cost-effective manner.

Unfortunately, pharmacy benefit managers (PBMs) have limited the positive impact that MIPs have on patient care through mandates that require oral oncolytics to be dispensed from external mail order pharmacies.[2]

PBMs also have made it more difficult to provide services at the point of care with additional requirements for MIPs to remain in their respective networks.[3]

The dynamic between MIPs and PBMs has evolved into an ever-changing landscape. As of 2016, Express Scripts, Inc. began requiring multiple MIPs to recredential as specialty pharmacies.

The recredentialing process requires MIPs to submit policies/procedures, inventory records, obtain external third-party accreditation if not accredited, and pay additional fees to participate "in network."

Other PBMs, including Optum Rx and Rx Advance, required further mandates that include dual specialty pharmacy accreditation through approved programs.

The process for credentialing and/or accreditation can be quite tedious, requiring numerous hours to prepare policies, update procedures and prepare for on-site surveys.

Furthermore, the MIP model doesn't always align with the traditional specialty pharmacy model, thus presenting additional challenges for MIPs to achieve accreditation.

Firms that provide specialty pharmacy accreditation for MIPs include the Accreditation Commission for Health Care (ACHC), Utilization Review Accreditation Commission (URAC), Center for Pharmacy Practice Accreditation (CPPA) and The Joint Commission.

NCODA has listened to the concerns of its members and has formed a credentialing committee to address these issues.

Committee members have real-world experience with specialty pharmacy credentialing and accreditation. Their shared ideas have led to the development of several resources which have been designed to aid NCODA members in accomplishing accreditation while reducing stress.

Resources include templates for required policies, best practices for achieving accreditation and a listserv to facilitate communication between NCODA members.

The credentialing committee continues to work on providing additional resources that will aid MIPs in achieving their credentialing and networking goals.

Recently, NCODA has collaborated with the American Society of Clinical Oncology (ASCO) to develop Oral Oncology Dispensing Standards for enhancing the Quality Oncology Practice Initiative (QOPI) Certification program.

The goal for this partnership is to provide high-level dispensing criteria and benchmarks for MIPs certifying through the ASCO/QOPI program.

These new standards will better address the unique aspects of a MIP in community practices with the objective of leveraging inclusion with PBM specialty networks.

For more information on credentialing, contact the credentialing committee at **contact@ncoda.org**.

NCODA members are also encouraged to share their expertise by joining the credentialing committee online at **www.ncoda.org/committees**.

▲ **Michael Brodersen**, PharmD, is the manager of NCS Outpatient Pharmacy, affiliated with Nebraska Cancer Specialists in Omaha, Nebraska.

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ESTIMATING 2019 OUT-OF-POCKET COST OF ORAL MEDICATIONS FOR METASTATIC RENAL CELL CARCINOMA FOR MEDICARE PART D MEMBERS

By Eric P. Borrelli, PharmD, MBA, & Conor G. McGladrigan, PharmD

In 2019, approximately 74,000 patients will be diagnosed with kidney cancer in the United States and approximately 15,000 patients will die from the disease.[1]

In total, there are approximately 500,000 patients living with kidney cancer in the U.S.[2] Renal cell carcinoma (RCC), which is a type of kidney cancer, comprises approximately 80% of adults cases in the U.S.[3]

The median age at diagnosis is 64 years; the five-year survival rate is 74% and heavily influenced by stage of disease.[2,4] Patients with localized disease have a 93% survival rate compared to patients with stage IV, who have a 12% five-year survival.[2]

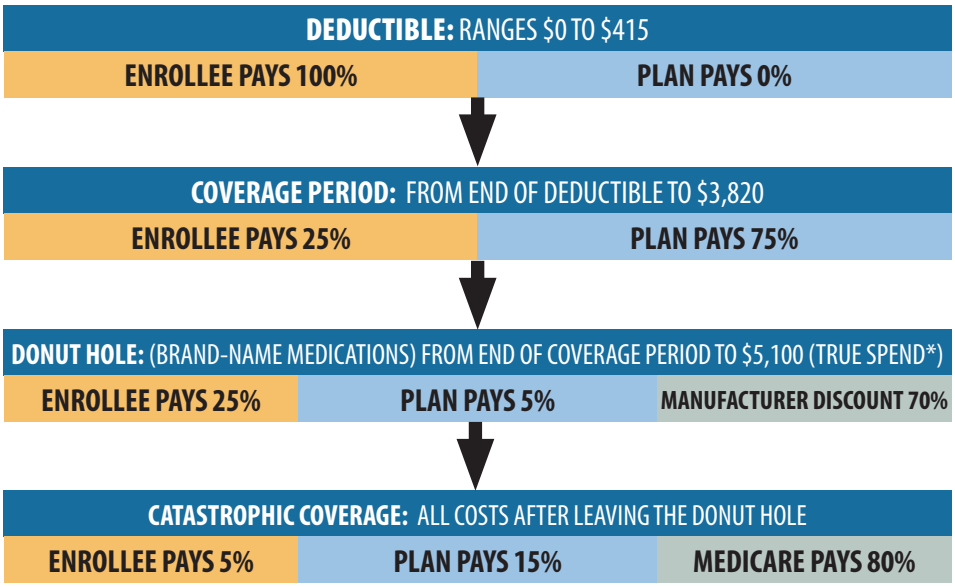
In addition to the poor prognosis of late-stage kidney cancer, many patients are confronted with the exorbitant out-of-pocket (OOP) costs for oral medications used to treat their disease as the cost of oncology drugs have increased dramatically in recent years.[5,6]

We sought to estimate the out-of-pocket cost specifically for Medicare Part D members, assessing guideline-preferred first-line oral medications for relapsed stage IV RCC with clear cell and non-clear cell histology.

We utilized the Medicare.gov Medicare Plan Finder to estimate patient OOP costs for oral medications for relapsed stage IV RCC.[7] Out-of-pocket cost was calculated based on the 2019 Medicare Part D cost-sharing structure (Figure 1).[8]

Two different scenarios were conducted to assess patient OOP cost: January Start and November Start. These two time points were chosen to illustrate differences in patient OOP cost depending on if a patient started therapy in the beginning of the year or near the end of the year.

FIGURE 1: STANDARD MEDICARE PART D PLAN DESIGN FOR THE YEAR 2019



**True Spend: Total amount paid out-of-pocket by enrollee plus discount applied by manufacturer*

Costs were calculated with the assumption that the patient was starting treatment on the first calendar day of the month (Jan. 1 and Nov. 1) with treatment continuing for a total of 12 months to illustrate the yearly OOP cost of treatment.

Oral treatments were selected based on National Comprehensive Cancer Network (NCCN) guidelines preferred treatment regimens for relapsed/stage IV RCC.[4]

The treatment options consisted of pazopanib, sunitinib, axitinib and cabozantinib (Table 1). The doses and regimens used in the analysis were derived from clinical trials.[9-12]

TABLE 1: METASTATIC RENAL CARCINOMA ORAL MEDICATION REGIMENS

BRAND	GENERIC	DIRECTIONS
Votrient	Pazopanib	800 mg by mouth once daily
Sutent	Sunitinib	50 mg by mouth once daily (six-week cycles: four weeks on, two weeks off)
Inlyta	Axitinib	10 mg by mouth twice daily
Cabometyx	Cabozantinib	60 mg by mouth once daily

Four states – Massachusetts, California, Florida and Minnesota – were randomly selected to sample different geographic regions and depict the difference in OOP cost for patients in different states. The Medicare Part D plan with the

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TABLE 2: MONTHLY OUT-OF-POCKET COST PER MEDICATION JANUARY START

MEDICATION	State	January	February	March	April	May	June	July	August	September	October	November	December	Annual OOP
Axitinib	Mass.	$2,621	$777	$777	$777	$777	$777	$777	$777	$777	$777	$777	$777	$11,168
Axitinib	Calif.	$2,694	$812	$812	$812	$812	$812	$812	$812	$812	$812	$812	$812	$11,626
Axitinib	Fla.	$2,652	$769	$769	$769	$769	$769	$769	$769	$769	$769	$769	$769	$11,111
Axitinib	Minn.	$2,671	$789	$789	$789	$789	$789	$789	$789	$789	$789	$789	$789	$11,350
Cabozantinib	Mass.	$2,778	$934	$934	$934	$934	$934	$934	$934	$934	$934	$934	$934	$13,052
Cabozantinib	Calif.	$2,871	$988	$988	$988	$988	$988	$988	$988	$988	$988	$988	$988	$13,739
Cabozantinib	Fla.	$2,847	$964	$964	$964	$964	$964	$964	$964	$964	$964	$964	$964	$13,451
Cabozantinib	Minn.	$2,817	$934	$934	$934	$934	$934	$934	$934	$934	$934	$934	$934	$13,091
Pazopanib	Mass.	$2,510	$666	$666	$666	$666	$666	$666	$666	$666	$666	$666	$666	$9,836
Pazopanib	Calif.	$2,586	$704	$704	$704	$704	$704	$704	$704	$704	$704	$704	$704	$10,330
Pazopanib	Fla.	$2,569	$687	$687	$687	$687	$687	$687	$687	$687	$687	$687	$687	$10,126
Pazopanib	Minn	$2,558	$676	$676	$676	$676	$676	$676	$676	$676	$676	$676	$676	$9,994
Sunitinib	Mass.	$2,819	$975	$0	$975	$975	$0	$975	$975	$0	$975	$975	$0	$9,644
Sunitinib	Calif.	$2,913	$1,031	$0	$1,031	$1,031	$0	$1,031	$1,031	$0	$1,031	$1,031	$0	$10,130
Sunitinib	Fla.	$2,888	$1,005	$0	$1,005	$1,005	$0	$1,005	$1,005	$0	$1,005	$1,005	$0	$9,923
Sunitinib	Minn.	$2,872	$989	$0	$989	$989	$0	$989	$989	$0	$989	$989	$0	$9,795

RENAL CELL CARCINOMA

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largest number of enrollees in each state was selected for the analysis.[13]

The patient OOP cost of treatment varied based on medication prescribed and geographic location.

For January starts, the OOP costs were highest for cabozantinib in all four states, ranging from $13,052 to $13,739 followed by axitinib ($11,111 to $11,626), pazopanib ($9,836 to $10,330) and sunitinib ($9,644 to $10,130) (Table 2).

A November-start resulted in an additional 12-month OOP cost of $1,844 to $1,883, varying based on the medication and geographic location. The increase in OOP cost is due to patients having to restart the Medicare Part D cost-sharing structure again in January instead of the remaining 10 months staying in the catastrophic coverage period.

Patient OOP cost burden substantially increased if treatment was initiated at the end of a calendar year compared to initiating therapy at the start of a new year.

Axitinib prescribing information allows for a dose increase up to 10 mg twice daily if patients do not experience grade 2 or worse adverse reactions.[8] As such, increased doses of axitinib were not included in our primary analysis.

However, if patients were on axitinib at the highest allowable dose of 10 mg twice daily, their OOP cost would have ranged from $20,350 in Florida to $21,370 in California.

The cost per geographic location was based on the health plan in each state with the highest number of enrollees, and may not accurately represent the cost of treatment for everyone in these states.

In addition, these analyses were conducted under the assumption that patients stay on the medication for the full year with 100% adherence at the initial starting dose without dose modification.

Rebates and financial assistance

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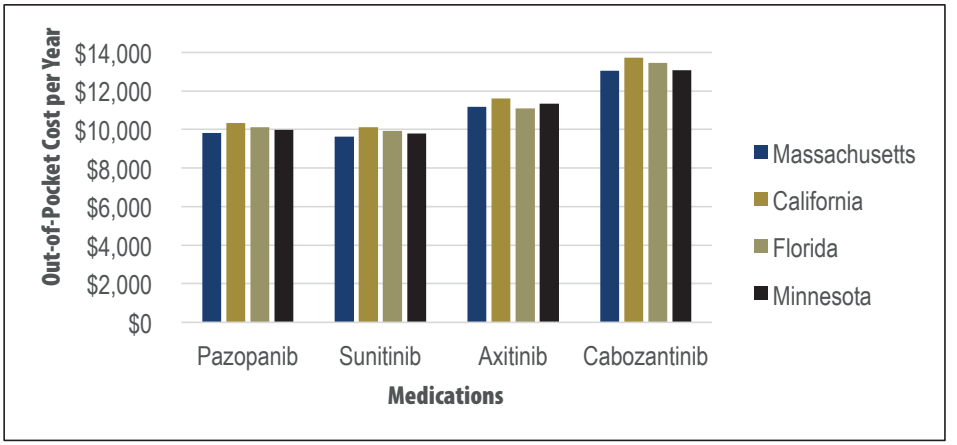
In summary, Medicare Part D plans require substantial OOP costs for all guideline preferred oral therapies in relapsed, stage IV RCC, ranging from $9,644 to $15,622 for 12 months of therapy.

FIGURE 2: YEARLY OUT-OF-POCKET COST PER MEMBER: JANUARY START



RENAL CELL CARCINOMA

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for patients were not included when conducting these analyses. Oftentimes manufacturers have wonderful financial assistance resources available for patients via their websites.

Other limitations include the fact that all patients were assumed to start therapy on the first day of the month, and dose interruptions, dose delays and dose modifications for all medications were not accounted for.

In summary, Medicare Part D plans require substantial OOP costs for all guideline preferred oral therapies in relapsed, stage IV RCC, ranging from $9,644 to $15,622 for 12 months of therapy.

Factors associated with differences in OOP cost include geographic region, medication type and month treatment was initiated, with the latter having the most substantial impact on patient OOP spending.

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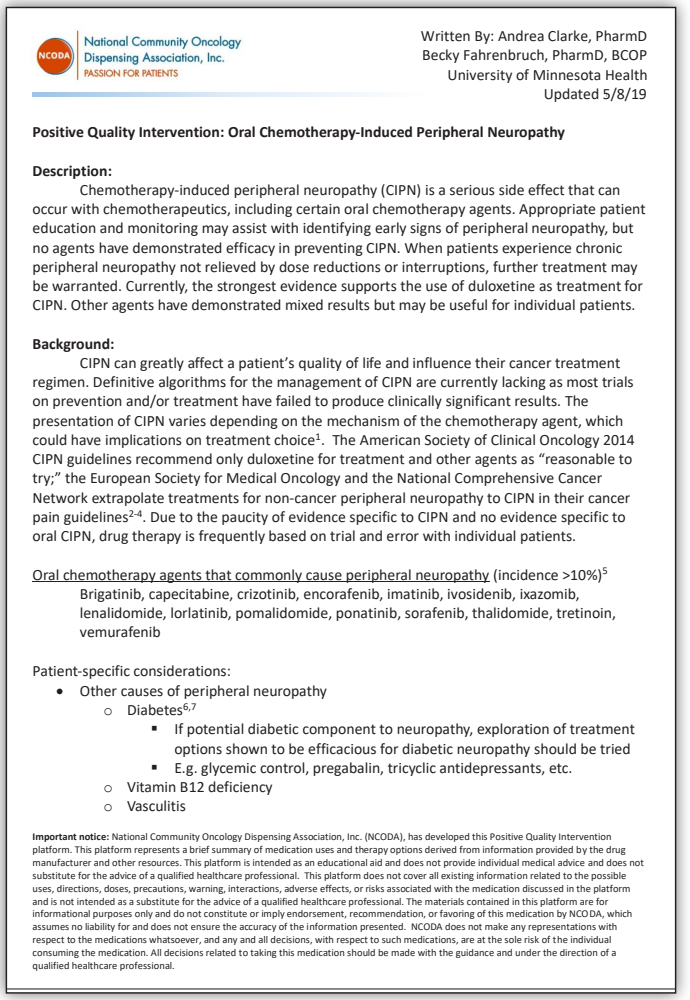
PQI PEER-REVIEWED DOCUMENTS PROVIDE CLINICAL GUIDANCE

Cancer care is a dynamic and ever-changing field. Advancing science has led to numerous treatment options researched and approved in oncology.

While these therapies are offering new hope for patients, they also create challenges for healthcare providers who must learn how to properly recommend, educate and manage patients.

In an effort to promote higher quality patient care, NCODA created the Positive Quality Intervention (PQI) initiative as a peer-reviewed clinical guidance document for healthcare providers.

By providing quality standards and effective practices around a specific aspect of cancer care, PQIs equip the multidisciplinary care team with a sophisticated and simple-to-use resource for managing patients receiving oral or intravenous oncolytics.



National Community Oncology Dispensing Association, Inc.
PASSION FOR PATIENTS

Written By: Andrea Clarke, PharmD
Becky Fahrenbruch, PharmD, BCOP
University of Minnesota Health
Updated 5/8/19

Positive Quality Intervention: Oral Chemotherapy-Induced Peripheral Neuropathy

Description:

Chemotherapy-induced peripheral neuropathy (CIPN) is a serious side effect that can occur with chemotherapeutics, including certain oral chemotherapy agents. Appropriate patient education and monitoring may assist with identifying early signs of peripheral neuropathy, but no agents have demonstrated efficacy in preventing CIPN. When patients experience chronic peripheral neuropathy not relieved by dose reductions or interruptions, further treatment may be warranted. Currently, the strongest evidence supports the use of duloxetine as treatment for CIPN. Other agents have demonstrated mixed results but may be useful for individual patients.

Background:

CIPN can greatly affect a patient's quality of life and influence their cancer treatment regimen. Definitive algorithms for the management of CIPN are currently lacking as most trials on prevention and/or treatment have failed to produce clinically significant results. The presentation of CIPN varies depending on the mechanism of the chemotherapy agent, which could have implications on treatment choice[1]. The American Society of Clinical Oncology 2014 CIPN guidelines recommend only duloxetine for treatment and other agents as "reasonable to try;" the European Society for Medical Oncology and the National Comprehensive Cancer Network extrapolate treatments for non-cancer peripheral neuropathy to CIPN in their cancer pain guidelines[2-4]. Due to the paucity of evidence specific to CIPN and no evidence specific to oral CIPN, drug therapy is frequently based on trial and error with individual patients.

Oral chemotherapy agents that commonly cause peripheral neuropathy (incidence >10%)[5]

Brigatinib, capecitabine, crizotinib, encorafenib, imatinib, ivosidenib, ixazomib, lenalidomide, lorlatinib, pomalidomide, ponatinib, sorafenib, thalidomide, tretinoin, vemurafenib

Patient-specific considerations:

- Other causes of peripheral neuropathy
  - Diabetes[6,7]
    - If potential diabetic component to neuropathy, exploration of treatment options shown to be efficacious for diabetic neuropathy should be tried
    - E.g. glycemic control, pregabalin, tricyclic antidepressants, etc.
  - Vitamin B12 deficiency
  - Vasculitis

Important notice: National Community Oncology Dispensing Association, Inc. (NCODA), has developed this Positive Quality Intervention platform. This platform represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and does not provide individual medical advice and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

PQIs foster improved care for patients through appropriate identification and selection, increasing speed to therapy, reducing cost and hospitalization and by improving adherence techniques for patients.

PQIs are free to access on the NCODA website so that all healthcare professionals have the opportunity to help their patients benefit most from their anti-cancer treatments.

Currently, 32 PQI documents are available with the total number expected to exceed 40 by the end of 2019.

Categorized by "Drug," "Disease" or "Supportive Care," the information contained within the PQIs is also searchable on the PQI webpage to quickly provide the needed information to the user. As these documents move from a topic idea to a finished product, the PQI Committee ensures that each one undergoes a rigorous, four-phase peer-review process before publication.

Medical accuracy is further heightened by working with medical affairs teams of drug manufacturers when appropriate. Once the PQI Chairs provide their approval, the document is reviewed by a medical oncologist for a final approval.

Lastly, in some instances, a PQI in Action article is created to evaluate how the finished PQI document is implemented as a resource tool at a particular treatment center. The article demonstrates how information exchange occurs via the PQI, thereby increasing communication across the medically integrated team and leading to specific, positive patient outcomes.

Although many PQIs focus on one particular treatment option, others differ and look at general topics, such as the PQI for Oral Chemotheray-Induced Peripheral Neuropathy. **The first page of the four-page document appears at left.**

The Positive Quality Intervention initiative has brought value to medically integrated care teams across the country. Through this medium, NCODA brings awareness to specific aspects of patient care and promote improved patient outcomes.

Furthermore, we recommend a wider adoption of new practice protocols to utilize this clinical guidance information and employ the principles contained within all PQI documents to deliver improved patient outcomes.

▲ If you would like more information about Positive Quality Intervention (PQI) documents, have interest in authoring a new PQI, or would like to join the PQI Review Committee, please email us at contact@ncoda.org.

CONTRIBUTING TO THE PHARMACY PROFESSION WHILE STILL A STUDENT

By Seanna I. Miller
PharmD Candidate

November 14, 2016, was a sunny winter day. A day that my mother had been dreading since her cancer diagnosis three weeks earlier. The first day of her chemo treatment.

It was the start of a battle my family and I knew would be difficult, thought would be long and hoped would be successful.

Her infusion started at 8 a.m. By noon, she was holding her chest, gasping that she couldn't breathe well. By 8 p.m., she was intubated in the ICU. Six days later, she passed away due to chemotoxicity.

As I said goodbye to her in that same ICU room, the words oncology, chemotherapy and safety took on a deeper, more profound meaning for me.

Six months later, I began my pharmacy school journey. But it did not take long before I started to find myself feeling unfulfilled by the limited opportunities outside of the pharmacy curriculum.

The classroom had become a repetitive daily routine of "class, study, test, class, study, test." Outside of the classroom, extracurricular involvement followed a repetitive routine of its own: student organizations run by students for students.

Unfortunately, such routines never allowed me to run with ideas, interact with medical practicing professionals or contribute to change. For me, those were critical prerequisites of becoming the pharmacist I aspired to be.

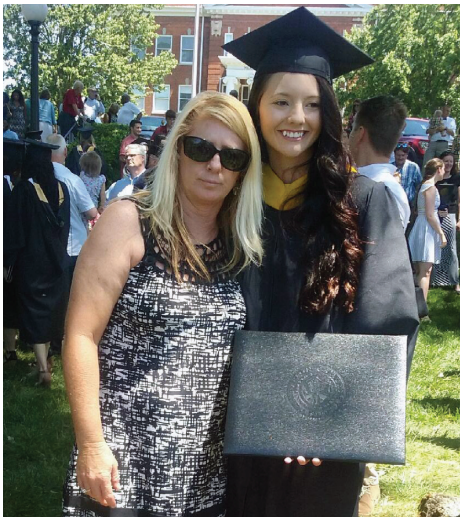


PHOTO PROVIDED BY SEANNA MILLER

Seanna Miller and her mother, Crystal, celebrate Seanna's graduation from Anderson University in South Carolina.

Then I learned about NCODA, and everything changed. I was immediately intrigued by NCODA's focus on oncology and the patient safety goals it was working so hard to promote.

NCODA has given me the fulfillment I was looking for during my pharmacy school journey.

Working alongside Jake Dygert, a classmate who introduced me to NCODA, I became involved in establishing NCODA's very first Professional Student Organization in January 2019 at South University in Columbia, S.C.

It was a true honor to be part of this opportunity, and I have been blessed to be able to help champion patient safety during my involvement. Oncology safety has become something very close to my heart since losing my mother to chemotoxicity.

And while my contributions to NCODA alone may not prevent such an unfortunate event, they can help decrease the chances of occurrence and raise awareness of how important chemotherapy safe practices, oral or infused, truly are.

Our NCODA student chapter also has provided me with many ways to get involved with my future profession. For example, during my NCODA journey so far, I have:

- Organized nationwide data;
- Attended many learning events live and remotely;
- Met numerous professionals in the specific areas of pharmacy that interest me; and
- Been allowed to contribute to the positive growth of pharmacy as a student in a way that would have otherwise not been an option.

NCODA has given me the fulfillment I was looking for during my pharmacy school journey. NCODA has let me work on perfecting knowledge and skills as I obtain them, and allowed me to make a difference in the profession as I pursue it.

As NCODA establishes more Professional Student Organization chapters, we hope that these chapters will give other pharmacy students like Jake and myself the fulfillment they seek.

Our vision is to get students inspired to be involved in the organization because it sparks a true interest, lets them pursue unique ideas and goals without the limitation of the "student" title, and helps remind them why they started their journey in the first place!

This article is dedicated in loving memory to my mother, Crystal Miller.

Seanna Miller is a third-year pharmacy student at South University in Savannah, Georgia, and a founding member of the school's NCODA Professional Student Organization chapter.

Empowering
YOUR EDUCATION

NCODA PROFESSIONAL STUDENT ORGANIZATION

NCODA is collaborating with universities and colleges nationwide to offer pharmacy students membership into a professional organization that is centered around advancing NCODA's mission of improving patient care.

The NCODA Professional Student Organization was established for students interested in oncology pharmacy, association management & industry leadership.

BENEFITS

- Opportunities to attend NCODA national meetings & present research
- Increased networking opportunities with clinical & industry professionals
- Participation in community service events through NCODA-led initiatives & partnerships
- Opportunities to help create new educational materials that will aid cancer patients nationwide

ESTABLISHED CHAPTERS

- Midwestern University Chicago College of Pharmacy
- South University School of Pharmacy
- Texas Tech University Health Sciences Center School of Pharmacy
- University of North Texas Health Science Center
- University of Rhode Island College of Pharmacy
- Washington State University College of Pharmacy and Pharmaceutical Sciences

FOR MORE INFORMATION OR TO SUGGEST NEW CHAPTERS

- Visit **www.ncoda.org/professional-student-organizations**
- Email Stephen Ziter at **stephen.ziter@ncoda.org**

NEW FDA ORAL ONCOLOGY DRUG APPROVALS FOR 2Q19 AND 3Q19

By Kirollos Hanna, PharmD, BCPS, BCOP, & Derek Gyori, PharmD, BCOP

ERDAFITINIB (BALVERSA®)

On April 12, the Food and Drug Administration (FDA) granted accelerated approval to erdafitinib (BALVERSA, Janssen Pharmaceutical Companies) for patients with locally advanced or metastatic urothelial carcinoma (mUC), with susceptible FGFR3 or FGFR2 genetic alterations, that has progressed during or following platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.[1]

Erdafitinib approval was based on data from a cohort of 87 patients enrolled on Study BLC2001, a multicenter, open-label, single-arm trial.[1,2] Objective response rate (ORR) was 32.2% (95% CI:22.4, 42.0), with complete responses in 2.3% and partial responses in 29.9%. Median response duration was 5.4 months (95% CI: 4.2, 6.9). Responders included patients who had previously not responded to anti PD-L1 or PD-1 treatment. Patients received erdafitinib at a starting dose of 8 mg once daily with a dose increase to 9 mg daily in those whose serum phosphate levels were below the target of 5.5 mg/dL, between days 14 and 17. The starting dose was increased to 9 mg daily in 41% of the patients. The most common adverse reactions reported in at least 40% of patients were increased serum phosphate, stomatitis, fatigue, increased serum creatinine, diarrhea, dry mouth, onycholysis, increased alanine aminotransferase, increased alkaline phosphatase and decreased sodium. Erdafitinib can cause ocular disorders. Central serous retinopathy or retinal pigment epithelial detachment resulting in visual field defect was reported in 25% of patients.

FGFR alterations should be assessed prior to initiating therapy with erdafitinib using the therascreen® FGFR RGQ RT-PCR Kit. The recommended initial dose of erdafitinib is 8 mg orally once daily taken with or without food. Between days 14 and 21 of cycle 1, the dose should be increased to 9 mg once daily as long as serum phosphate levels remain below 5.5 mg/dL and there are no ocular disorders or Grade ≥ 2 adverse reactions.[2]

IVOSIDENIB (TIBSOVO®)

On May 2, the FDA approved ivosidenib (TIBSOVO, Agios Pharmaceuticals, Inc.) for newly diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation in patients who are greater than 75 years old or have comorbidities that preclude the use of intensive therapy.[1]

Already bearing an indication for relapsed/refractory AML, ivosidenib received approval as first line therapy based on the results from an open-label, single-arm, multicenter clinical trial.[1,3] Efficacy for ivosidenib was determined based on the rate of complete remission (CR) and complete remission with partial hematologic remission(CRh), the duration of response, and conversion of transfusion dependence to transfusion independence. Of the 28 subjects,

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FDA APPROVALS

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12 (42.9%) subjects achieved CR and CRh (95% CI: 24.5-62.8). Seven (41.2%) of the 17 patients who were transfusion dependent achieved transfusion independence for at least eight weeks. The most common side effects observed were diarrhea, fatigue, edema, decreased appetite, leukocytosis, nausea, arthralgia, abdominal pain, dyspnea, differentiation syndrome and myalgia. Ivosidenib does possess a Boxed Warning for the risk of differentiation syndrome which may be life-threatening or fatal.

The IDH1 mutation should be confirmed using the Abbott RealTimeTM IDH1 Assay prior to using ivosidenib. The recommended dose of ivosidenib for AML is 500 mg orally once daily with or without food until disease progression or unacceptable toxicity and is recommended to be continued for at least six months to allow time for a clinical response.[1,3]

VENETOCLAX (VENCLEXTA®)

On May 15, the FDA approved venetoclax (VENCLEXTA, AbbVie Inc. and Genentech Inc.) for adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in combination with obinutuzumab.[1]

CLL14, a randomized (1:1), multicenter, open label, actively controlled trial established the efficacy and safety of the drug combination.[1,4] Patients with previously untreated CLL with coexisting medical conditions were assigned to venetoclax in combination with obinutuzumab (VEN+G) versus obinutuzumab in combination with chlorambucil (GClb). The trial demonstrated a statistically significant improvement in progression-free survival (PFS) for patients who received VEN+G compared with those who received GClb (HR 0.33; 95% CI: 0.22, 0.51; p<0.0001). Median PFS was not reached in either arm after a median follow-up duration of 28 months. The ORR was 85% in VEN+G arm compared to 71% in GClb arm, p=0.0007. The trial also demonstrated statistically significant improvements in rates of minimal residual disease negativity in bone marrow and peripheral blood. In CLL/SLL, the most common adverse reactions (≥ 20%) for venetoclax when administered with obinutuzumab, rituximab or as monotherapy were neutropenia, thrombocytopenia, anemia, diarrhea, nausea, upper respiratory tract infection, cough, musculoskeletal pain, fatigue and edema.

On Cycle 1 Day 22, venetoclax should be initiated according to the five-week ramp-up schedule and continued at 400 mg orally once daily beginning from Cycle 3, Day 1.[4]

RUXOLITINIB (JAKAFI®)

On May 24, the FDA granted approval for ruxolitinib (JAKAFI, Incyte Corporation) for steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients older than 12 years old.[1]

Efficacy for ruxolitinib was determined based on the results of an open-label, single-arm, multicenter clinical trial.[1,5] The primary endpoints include Day 28 overall response rate (ORR) including complete response, very good partial response, and partial response based on the Center for International Blood and Marrow Transplant Research criteria, and response duration. Day 28 ORR was 100% for Grade 2 GVHD, 40.7% for Grade 3 GVHD, and 44.4% for Grade 4 GVHD. The median response duration, calculated from Day 28 response to progression, new salvage therapy for acute GVHD, or death from any cause was 16 days (95% CI: 9-83), and the median time from Day 28 response to either death or need for new therapy for acute GVHD was 173 days.

The recommended dose of ruxolitinib for acute GVHD is 5 mg orally twice daily with or without food and can be increased to 10 mg orally twice daily after three days in the absence of toxicity.[5]

ALPELISIB (PIQRAY®)

On May 24, the FDA approved apelisib (PIQRAY, Novartis Pharmaceutical Corporation) in combination with fulvestrant for post-menopausal women, and men with hormone-receptor (HR) positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test after progression on endocrine therapy.[1]

The SOLAR-1 trial was a phase-3, randomized, double-blind, placebo-controlled clinical trial that evaluated apelisib plus fulvestrant versus placebo plus fulvestrant in patients with HR-positive, HER2-negative advanced or metastatic breast cancer patients who had progressed on endocrine therapy.[1,6] The primary efficacy outcome was investigator-assessed median PFS. The estimated median PFS in the alpelisib plus fulvestrant arm was 11.0 months (95% CI: 7.5-14.5) compared with 5.7 months (95% CI: 3.7-7.4) in the placebo plus fulvestrant arm (HR 0.65; 95% CI: 0.50-0.85; p=0.001). Overall survival data were not mature at the time of analysis. No PFS benefit was observed in patients PIK3CA-negative tumors. The most common adverse reactions including laboratory abnormalities on the alpelisib plus fulvestrant arm were increased glucose, increased creatinine, diarrhea, rash, decreased lymphocyte count, increased gamma glutamyl transferase, nausea, increased alanine aminotransferase, fatigue, decreased hemoglobin, increased lipase, decreased appetite, stomatitis, vomiting, decreased weight, decreased calcium, decreased glucose, prolonged activated partial thromboplastin time (aPTT) and alopecia.

An FDA-approved diagnostic test must be used to identify the presence of a PIK3CA mutation, such as the therascreen® PIK3CA RGQ PCR Kit, (QIAGEN Manchester, Ltd.) The recommended alpelisib dose is 300 mg (two 150 mg film-coated tablets) taken orally, once daily, with food. When given in combination with apelisib, the recommended dose of fulvestrant is 500 mg administered intramuscularly on Days 1, 15, and 29, and once monthly thereafter.[1]

LENALIDOMIDE (REVLIMID®)

On May 28, the FDA approved lenalidomide (REVLIMID, Celgene Corp.) in combination with a rituximab product for previously treated follicular lymphoma (FL) and previously treated marginal zone lymphoma (MZL).[1]

Approval was based on two clinical trials: AUGMENT and MAGNIFY.[7,8] In AUGMENT patients were randomized (1:1) to receive lenalidomide and rituximab or rituximab and placebo. This trial demonstrated a median PFS of 39.4 months (95% CI: 22.9, NE) in the lenalidomide arm and 14.1 months (95% CI: 11.4, 16.7) in the placebo-containing arm (HR 0.46; 95% CI: 0.34, 0.62; p<0.0001); ORR for patients with FL was 80% (118/147; 95% CI: 73%, 86%) in the lenalidomide arm compared with 55.4% (82/148; 95% CI: 47%, 64%) in the control arm; ORR for patients with MZL was 65% (20/31; 95% CI: 45%, 81%) compared with 44% (14/32; 95% CI: 26%, 62%), respectively. The single arm component of MAGNIFY demonstrated an ORR of 59% (104/177; 95% CI: 51%, 66%) for patients with FL in patients that received 12 induction cycles of lenalidomide and rituximab. Median response duration was not reached with a median follow-up of 7.9 months (95% CI: 4.6, 9.2). For patients with MZL, the ORR by investigator assessment was 51% (23/45; 95% CI: 36%, 66%). Median response duration was not reached with a median follow-up of 11.5 months (95% CI: 8.0, 18.9). Across both trials, the most common adverse reactions occurring in at least 20% of patients were neutropenia, fatigue, diarrhea, constipation, nausea and cough.

The recommended lenalidomide dose for FL or MZL is 20 mg once daily orally on Days 1-21 of repeated 28-day cycles for up to 12 cycles.[9]

GILTERITINIB (XOSPATA®)

On May 29, the FDA approved the addition of OS data in labeling for gilteritinib (XOSPATA,

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FDA APPROVALS

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Astellas Pharma US, Inc.), indicated for adult patients who have relapsed or refractory AML with a FLT3 mutation as detected by an FDA-approved test.[1] The median OS was 9.3 months for patients receiving gilteritinib and 5.6 months for those on the chemotherapy arm (HR 0.64; 95% CI: 0.49,0.83; 1 sided p-value=0.0004).

SELINEXOR (XPOVIO®)

On July 3, the FDA granted accelerated approval to selinexor (XPOVIO, Karyopharm Therapeutics) in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.[1]

Efficacy and safety were established from Part 2 of the STORM trial – a multicenter, single-arm, open-label study of patients with RRMM who had previously received three or more anti-myeloma treatment regimens.[1] ORR was 25.3% (95% CI: 16.4, 36), with one stringent complete responses, no complete response, four very good partial responses and 16 partial responses. The median time to first response was four weeks (range: 1 to 10 weeks). The median response duration was 3.8 months (95% CI: 2.3, not estimable). Common adverse reactions reported in at least 20% of patients include thrombocytopenia, fatigue, nausea, anemia, decreased appetite, decreased weight, diarrhea, vomiting, hyponatremia, neutropenia, leukopenia, constipation, dyspnea and upper respiratory tract infection.

The recommended selinexor dose is 80 mg in combination with dexamethasone taken orally on Days 1 and 3 of each week.[10]

DAROLUTAMIDE (NUBEQA®)

On July 30, the FDA approved darolutamide (NUBEQA, Bayer HealthCare) for the treatment of non-metastatic castration resistant prostate cancer.[1] Darolutamide is an androgen receptor (AR) inhibitor. Darolutamide competitively inhibits androgen binding, AR nuclear translocation, and AR mediated transcription, which ultimately decreases prostate cancer cell proliferation.[11]

The ARAMIS trial was a multicenter, double-blind, placebo-controlled clinical trial that evaluated darolutamide in patients with non-metastatic castration resistant prostate cancer. In addition to darolutamide, all patients received a gonadotropin-releasing hormone (GnRH) analog concurrently or had a previous orchiectomy. The primary endpoint was metastasis free survival (MFS), defined as the time from randomization to first evidence of distant metastasis or death from any cause within 33 weeks after the last evaluable scan, whichever occurred first. The median MFS was 40.4 months (95% CI 34.3 – not reached) for patients treated with darolutamide compared with 18.4 months (95% CI: 15.5 – 22.3) for those receiving placebo (hazard ratio 0.41; 95% CI: 0.34 - 0.50; p<0.0001). Overall survival data were not mature. The most common adverse effects seen in patients who received darolutamide were fatigue, back pain, arthralgia, diarrhea, hypertension, constipation, pain in extremity, anemia and rash. The seizure incidence was similar between darolutamide and placebo groups.[12]

The recommended darolutamide dose is 600 mg (two 300 mg tablets) administered orally twice daily with food. Patients should also receive a GnRH analog concurrently or should have had bilateral orchiectomy.[1,12]

PEXIDARTINIB (TURALIO®)

On Aug. 2, the FDA approved pexidartinib, (TURALIO, Daiichi Sankyo, Inc.), the first systemic therapy, for adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.[1]

The ENLIVEN trial was an international, multicenter, randomized (1:1), double-blind, placebo-controlled trial enrolling 120 patients with TGCT not amenable to surgical resection.[13] ORR was determined by an independent review committee at Week 25. After 25 weeks of treatment, the ORR was 38% (95% CI: 27, 50), with a 15% complete response rate and a 23% partial response rate. No patients receiving placebo had a response (p<0.0001). Twenty-two of 23 patients who responded and had been followed for a minimum of six months after the initial response maintained the response for ≥6 months. In addition, 13 of 13 patients who responded and had been followed for a minimum of 12 months after the initial response maintained the response for ≥12 months. Common side effects of pexidartinib were increased lactate dehydrogenase, increased aspartate aminotransferase, hair color changes, increased alanine aminotransferase, and increased cholesterol.

The recommended pexidartinib dose is 400 mg (two capsules) orally twice daily on an empty stomach.[1]

**FDA approvals for these quarters spanned through Aug. 8, 2019.*

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TIPS ON BUILDING YOUR 'BRAND' WITH ELECTED OFFICIALS

By Kathy Oubre, MS

Since the 2016 United States presidential election, civic engagement is at an all-time high with many constituents motivated to demand that their elected officials listen to them.

We certainly see this in healthcare reform, which remains high on the current administration's agenda. Nevertheless, this flurry of activity begs the question: How do I ensure that I'm effectively engaging with my members of Congress?

Kathy Oubre

Developing relationships with lawmakers and other government officials are fundamental to advancing policy goals. Of course, in-person meetings are best whether it is in the district or at their District of Columbia offices, but a well-crafted email or phone call can be effective, too.

Since very few of us have plans to live on Capitol Hill, it is best to have a combination of all three. Consider incorporating these ingredients for an effective relationship:

• **Obtain a meeting:** Get a time to meet with lawmakers, either in the district or at their offices. The best way to start is with a formal email and a follow-up call to their office. It works well if you have someone make the appointments in person. People don't like to say no to someone standing in front of them!

• **Do some basic research:** Read the member's biography, legislative history, Facebook page, etc. Try to understand the basis for their positions (i.e., voting record on related legislation, professional interests, committee assignments, tenure and constituent pressures.)

It is important to remember that while the healthcare issue we are meeting about is very important to us, legislators must balance our issue against everything else going on (i.e., an upcoming farm bill or oil/gas legislation) and how that impacts their constituents and the nation.

• **Prepare materials:** Bring concise and interesting materials to share. A single page which explains who you represent and the issue to be discussed may be all that you need. Save the bulky information for follow up emails.

• **Be prepared:** I distinctly remember my first meeting with Sen. Bill Cassidy of Louisiana, who is also a gastroenterologist and spent most of his medical career training interns. While I thought I was well-prepared and knowledgeable on my subject, I was unprepared for some of his more direct questions.

I later shared this experience with some of our physicians (whom Sen. Cassidy trained), which got quite a laugh because he was essentially treating me like an intern during grand rounds! Nowadays, I take a few extra steps in my meeting preparation which has allowed me to be a more effective advocate.

• **Share the stories:** Discussing facts and figures are important in these meetings, but so is the human element. Legislators want and need to know how policies will impact their constituents. Be prepared to share patient impact stories.

During my most recent trip to DC, we focused on Pharmacy Benefit Managers (PBMs). A patient's family came with me and they were able to share their mother's story of waiting more than 30 days for her medications due to struggles between the insurer and PBM with nine different legislators.

• **Seek first to understand, then to be understood:** Not every meeting will be a "win" where you are advancing policy; sometimes you are laying the educational foundation to advance policy later.

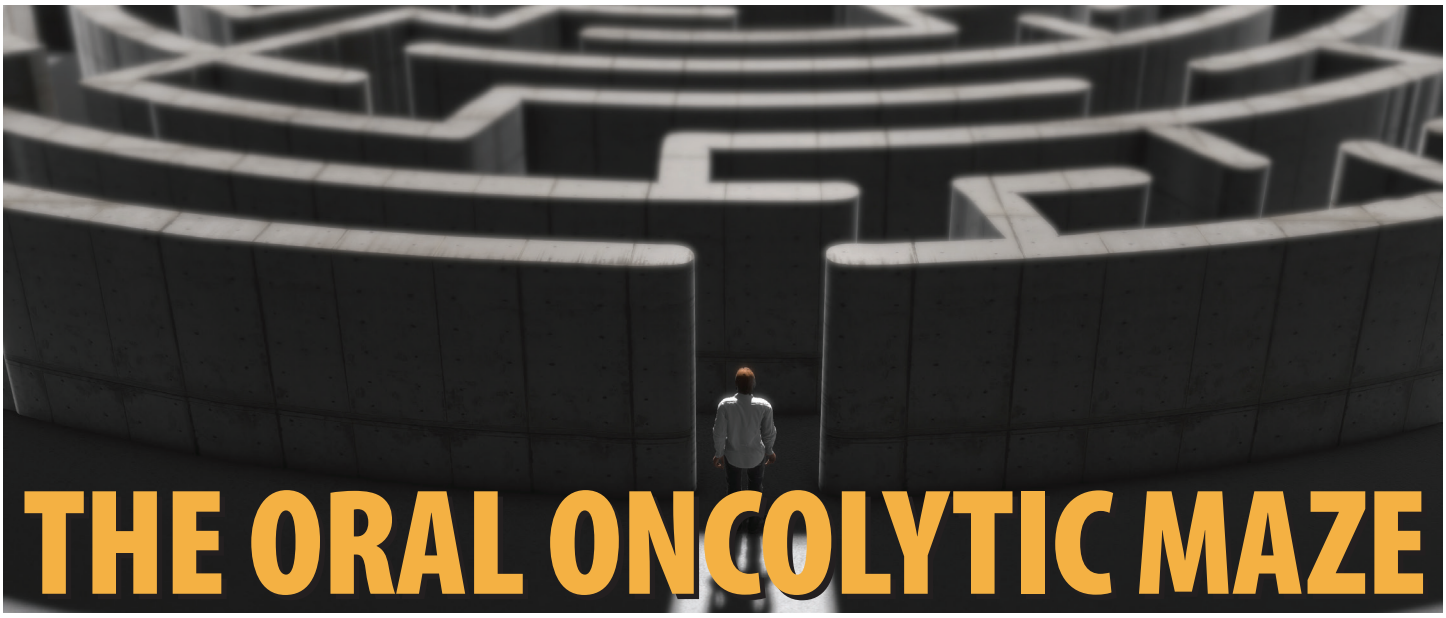
• **After the meeting, take care to follow up:** Follow through with any promises. Write a thank-you note or email. Record what you learned so you can track your relationships and find ways to connect in the district (i.e., invite them to spend time in your clinic meeting staff, patients and clinicians, and to attend upcoming town hall meetings).

Be available to elected officials of all parties and reach out to all reasonable people as you cultivate your working relationships. Not everyone will always agree with you or support you, but you are well-positioned if you are well-respected.

Your goal is to build your "brand" as a trusted and knowledgeable source on healthcare issues.

▲ **Kathy Oubre**, MS, is Chief Operations Officer at Pontchartrain Cancer Center in Covington, Louisiana.

PATIENT TRACKING TOOLS HELP MANAGE THE ORAL ONCOLYTIC MAZE



By Mary K. Anderson, BSN, RN, OCN, Martha Kuehle, BSN, RN, OCN, & Rachelle Mackey, RN, OCN

Navigating a growing number of patients who take oral oncolytics can be an overwhelming job.

Challenges nurses face with oral oncolytic management include confusing specialty pharmacy processes, prior authorization, patient financial assistance, patient education, start date documentation, scheduling of clinical monitoring parameters and patient adherence.

Keeping track of these multiple steps is necessary and tracking tools in the form of spreadsheets and checklists can assist nurses in preventing patients from "falling through the cracks" or "getting lost in the system."

Since the patient may not come to the clinic as often to receive their treatment, the medically integrated team must ensure the patient obtains the medication in a timely manner, takes the medication as directed and manages potential side effects appropriately.

By utilizing a tracking tool, nurses are able to keep track of patients throughout the continuum of their oral oncolytic regimen.[1]

When the decision is made for a patient to start an oral oncolytic, the nurse may alleviate some of the patient's burden by proactively tracking the acquisition process through collaboration with the pharmacy, insurance provider, financial advocates and the patient.

Once the nurse educates the patient in the clinic setting and the patient obtains the medication, the nurse must follow up to confirm the patient understands how to take the medication and document the start date.

Monitoring parameters should be scheduled in accordance with the start date. Based on when the patient begins

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TRACKING FORMS

The NCODA Nursing Committee created the **Initial Fill Tracking Form** and the **After the First Fill Tracking Form** to help track patients on oral chemotherapy.

FIRST FILL TRACKING FORM

DATE	PATIENT NAME	IDENTIFIER	PROVIDER	PHARMACY	TEACH	CONSENT	MEDICATION

AFTER THE FIRST FILL TRACKING FORM

PATIENT NAME	IDENTIFIER	ONCOLYTIC	START	CLINICAL PARAMETERS	WEEK 1	WEEK 2	WEEK 3	WEEK 4	MTH 2	MTH 3	REFILL	AUTH

MAZE

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taking the oral oncolytic, the nurse will plan outbound calls to the patient on a regular basis to promote adherence and symptom management.

Patients have reported that tailored education and follow-up calls reinforced their knowledge and understanding of their oral chemotherapy.[2]

In one study, implementation of a tracking program for oral chemotherapy led to a 72% reduction in emergency room visits by patients on oral chemotherapy care plans.[3]

In 2018, the NCODA Nursing Committee conducted a survey of nurses who manage patients taking oral oncolytics. The most requested assistance tool identified by the survey was a tracking form for following each patient taking oral cancer medications.

In April 2019, the Nursing Committee approved the "First Fill Tracking Form," followed by the "After the First Fill Tracking Form."

These forms include information deemed necessary by the committee members to track both during the acquisition phase and after the treatment is started. The nurse keeps track of patients by checking off each item when completed (i.e., education, informed consent, prior authorization and financial assistance).

Other information collected includes dispensing pharmacy, start date, and due dates for outbound calls and refills.

These patient tracking tools are just one of several planned initiatives. Future initiatives include a standardized "welcome letter" for patients starting an oral oncolytic, documentation resources and promotion of the oral oncolytic nurse navigator role.

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ENASIDENIB FOR IDH2 MUTATION-POSITIVE AML

By Jeff Klaus, PharmD, BCPS

The treatment of acute myeloid leukemia (AML) is advancing rapidly with a variety of agents recently receiving FDA approval.

Modern treatments produce a complete remission (CR) in most patients, however, some are refractory to initial treatment and many relapse after an initial response.[1,2] Thus, most patients eventually require additional therapy for relapsed/refractory AML (RR-AML).

Jeff Klaus

Much of the recent advancements in AML have come in the form of targeted therapies.

Enasidenib is a small molecule that enters the leukemic cells and inhibits the isocitrate dehydrogenase 2 (IDH2) enzyme.

IDH2 mutations occur in approximately 12% of patients with AML, and tend to increase in frequency with age.[3]

Mutations in IDH2 lead to several changes associated with differentiation arrest within hematopoietic cells and contribute to the characteristic appearance of immature myeloid cells seen in AML.[3]

A DIFFERENTIATING AGENT

By inhibiting mutant IDH2 enzymes, enasidenib appears to act primarily as a differentiating agent, as opposed to the cytotoxic effects of conventional chemotherapeutic agents, and helps to restore normal myeloid differentiation.[3]

While enasidenib is still a relatively new agent and the available data is limited, it has been FDA-approved for IDH2 mutation-positive RR-AML at a dose of 100 mg orally once daily given in continuous 28-day cycles.

A single-arm, phase 1/2 study included 109 IDH2 mutation-positive RR-AML patients who received the FDA-approved dose.

Patients were a median of 67 years of age, 32% were refractory to initial therapy, 23% were relapsed/refractory to ≥ 2 cycles of lower intensity therapy, 25% had relapsed within one year of initial therapy, and 11% had relapsed after a

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While not currently FDA-approved for front-line therapy, the National Comprehensive Cancer Network guidelines identify enasidenib as an option for patients with newly diagnosed IDH2-mutated AML who are unfit for intensive therapy.

ENASIDENIB

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hematopoietic transplant. The median number of enasidenib cycles received was five.

Although enasidenib was generally well-tolerated, the most common treatment-related treatment emergent adverse events (TEAEs) were indirect hyperbilirubinemia (38%) and nausea (23%).

The most common enasidenib-related grade ≥ 3 TEAEs were indirect hyperbilirubinemia (12%) and differentiation syndrome (DS, 6%).

Differential Syndrome occurred in 23 patients with a median onset of 48 days, was managed with systemic corticosteroids in most patients, and enasidenib was transiently held in 10 (43%) patients.

Consistent with enasidenib's mechanism of action, rates of hematologic toxicity were lower than expected with multi-agent chemotherapy regimens.

A CR was achieved in 20.2% of patients, and a CR with incomplete hematologic recovery (CRi) or incomplete platelet recovery (CRp) was 6.4%. Additionally, 2.8% of patients experienced a partial remission (PR), 9.2% had a morphologic leukemia free state (MLFS), and 53.2% had stable disease.

The median time to attain CR was 3.7 months, which is delayed compared to conventional multi-agent chemotherapy, emphasizing the importance of continuing enasidenib if toxicity and progressive leukemia are absent. The median duration of response was 8.8 months.[3]

NCCN GUIDELINES

While not currently FDA-approved for frontline therapy, the National Comprehensive Cancer Network (NCCN) guidelines identify enasidenib as an option for patients with newly diagnosed IDH2-mutated AML who are unfit for intensive therapy.

Fitness is an important consideration as many AML patients are of advanced age and may not tolerate conventional multi-agent chemotherapy regimens.

In a multicenter, open-label, single-arm study that enrolled patients with previously untreated IDH2-mutated AML who were not candidates for standard AML therapies, 12/39 (30.8%) experienced a response (18% CR, 3% CRi/CRp, 5% PR, 5% MLFS). The median age at study entry was 77 years, and enasidenib was well tolerated with patients receiving a median of six cycles.

The most common treatment-related TEAEs were indirect hyperbilirubinemia (31%), nausea (23%), fatigue (18%), decreased appetite (18%), rash (18%), and anemia (15%). Some patients experienced DS (13%), with a median onset of 48 days.[4]

In addition to being a single-agent treatment option for IDH2-mutated RR-AML and upfront therapy for patients unfit for intensive therapy, enasidenib is currently being studied in combination with other agents and, depending on the results of these studies, its use may expand in the future.

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MEDICAL CANNABINOIDS

By Merrill Norton, PharmD, DPh, ICCDP-D, Dillon Frazier, & Kendall Anderson

CBD: AN EFFECTIVE TREATMENT FOR CANCER PAIN?

The management of cancer pain has multiple options and controversies. Recently, cannabinoids are the topic of much discussion in pain management for patients with cancer.

The current evidence for cannabinoids as analgesics is limited and their use is weakly recommended.[1]

This review aims to help clinicians understand the most effective approaches for the use of medical cannabinoids which have been legally used in the U.S. since California's Compassionate Use Act of 1996.[2]

USE IN CHRONIC PAIN

Cannabis has demonstrated efficacy in chronic pain management in clinical trials as documented in the review by the National Academies of Science and Medicine.[3] Additionally, oral cannabinoids are shown to be effective in the treatment of chemotherapy-induced nausea and vomiting.

There is also conclusive evidence to support the improvement of patient-reported spasticity symptoms in patients with multiple sclerosis.[3]

Although this field of pharmaceutical development is relatively new, ongoing drug development indicates benefits from targeting endocannabinoid receptors.[4]

Currently, synthetic cannabinoids are in development to target allodynia and neuropathy in an effort to combat chronic pain. In the context of chronic pain, concerns are present regarding the prevalent use and misuse of opioid medications in treatment regimens.

Cannabis products may also serve a role in the treatment of opioid use disorder (OUD). Studies have shown patients using opioids for chronic pain decrease their opioid consumption by up to 40-60% and report fewer side effects with cannabis.

Interestingly, patients also reported an improvement in cognitive function. [5]

USE IN CANCER PAIN

Many patients with cancer experience unmanageable pain despite chronic opioid use.

In a randomized, placebo-controlled, graded-dose trial for opioid-treated

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CANNABINOIDS

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patients, participants were given nabiximols (fixed THC:CBD ratio) via oral mucosal spray at a prescribed dose. A decrease in pain was seen in these patients, especially at low and medium doses.[6]

Although the subjects remained on a fixed opioid dose, the researchers suggested that opioid doses could potentially be decreased.

It has also been postulated that cannabinoids could be an efficacious adjunctive treatment for cancer pain.

In a study of patients with advanced cancer, the use of a THC:CBD extract demonstrated a statistically significant reduction in pain severity. THC extract alone failed to demonstrate a reduction in pain severity.

In the trial extension, patients either received THC extract alone or THC:CBD extract for as long as they could tolerate the medication.

Over time, patients exhibited a slight reduction in cancer-related pain with the THC:CBD extract.[7,8]

Although there is limited data regarding the specific use of cannabinoids in cancer-related pain, reviews of current literature find that cannabinoids, such as nabiximols, are significantly associated with a decrease in cancer-related pain.[7,8]

Cannabinoids also have a prospective place in therapy for cancer-related nociceptive pain, endocannabinoid deficiencies and neuropathic pain.

Evidence supports the use of cannabinoids to treat non-cancer related nociceptive pain,[2] but the data is limited in treating nociceptive cancer pain associated with bone metastases.

In select patients,[2] there is potential for a natural endocannabinoid deficiency that could complicate cancer pain through comorbidities.

Neuropathic pain continues to be one of the leading sources of pain in patients undergoing cancer treatment, and some patients have experienced decreased levels of neuropathic pain following a cannabis-based regimen.[4]

Collaborating on this article for *Oncolytics Today* were (from left) Kendall Anderson, Merrill Norton and Dillon Frazier.

A 2014 study analyzed the effects of cannabinoid use in patients experiencing chemotherapy-induced cancer pain resulting from treatment regimens consisting of either paclitaxel, vincristine or cisplatin.

Five of the 20 patients in the trial experienced a two-point or greater reduction in the Numeric Rating Scale of Pain Intensity (NRS-PI) during treatment. Neuropathic pain is a common limitation of chemotherapy, and cannabinoids have the potential to improve both patient outcomes and quality of life.[7]

In two selective review articles, researchers examined studies in the literature regarding cannabinoids in cancer-related pain. It was concluded that cannabinoids, such as nabiximols, were significantly associated with a decrease in cancer-related pain.[9,10]

Overall, there are several review articles on the medical use of cannabinoids, but few are specific to cancer-related pain.

CONCLUSION

Cannabis-derived products may be effective in treating cancer-related pain, but further research is warranted regarding the efficacy and safety, pharmacokinetics, dosing parameters and delivery mechanisms of these products.

Advances in targeted drug mechanisms may be on the horizon. A major impediment to performing quality research is the current classification of cannabis as a Schedule 1 drug.

As more information is gathered regarding the use of cannabis, it will be imperative to integrate this information into clinical practice and provide education to healthcare teams.

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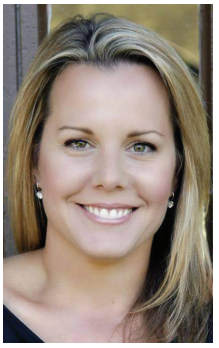
NURSE NAVIGATOR: ADVOCATE AND GUIDE FOR PATIENTS IN THE ADVANCED PROSTATE CANCER CLINICAL SETTING

By Anna McGrain, MSN, ANP-BC

The role of the nurse predates the mid-19th century. However, the birth of the professional nurse arose around the time of the Crimean War with Florence Nightingale as its founder.



Anna McGrain

It was during the war that Nightingale advocated for injured soldiers she was caring for and demanded significant improvements in the military hospital conditions.

She reorganized how care was delivered to patients and her efforts resulted in a significant and immediate drop in death rates within weeks. She was credited with saving thousands of lives and her research and publications later would result in establishing new nursing care standards.

Today, the nurse's role has expanded to include a wide range of responsibilities, but the foundation of the professional nurse's role is still as a patient advocate, just as it was for Nightingale.

As medical care has evolved over the years, so has nursing care. Nurses no longer just work in the hospital and trauma center. They now work in such settings as outpatient medical offices and surgery centers.

Medical care is also much more complicated than it was back then. We have regulations, guidelines, Medicare, private insurance, high cost specialty drugs, investigational research opportunities and much more.

A PARADIGM SHIFT

In urology today, we are providing more advanced medical management for men with advanced prostate cancer.

Our urologists, through innovative research and guidance from the National Comprehensive Cancer Network (NCCN) and the American Urological Association (AUA), are able to provide patients with cutting-edge care when there is evidence of biochemical recurrence, metastatic disease or castration resistance. In many cases, our care team follows patients from time of diagnosis through treatment. Our patients have grown to know and trust our team members.

Many urology offices have addressed this paradigm shift by creating specialty clinics within their practice to manage this growing population of patients.

Nurse navigators have become essential for managing the coordination of care for these patients. They are uniquely qualified based on their training and experience to ensure that all aspects of their patient's care and quality of life needs are addressed and met. Care coordination and patient advocacy cannot exist in the advanced prostate cancer domain without a nurse navigator.

DEVELOPING TRUST

Patients facing advanced prostate cancer know little to nothing of what obstacles they may face from the prognosis, quality of life and socioeconomic perspectives.

A savvy nurse navigator understands that getting to know the patient and their family is an important first step.

Nurse navigators visit with patients and their families to develop trust and empathy, as well as an understanding of who their patients are and what is most important to them. This establishes the foundation from which the nurse naviga-

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NURSE NAVIGATOR

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tor can begin supporting patient needs.

The nurse navigator can thus meld patient concerns with the plan of care established by the physician.

Finding resources to help patients progress smoothly on the established medical care plan is a key role for the nurse navigator.

Often times, financial support is a major factor to be considered. Even with Medicare, patients can face a large "donut-hole" deductible in order to complete treatments.

Many patients are not technologically savvy and do not understand the nuances of where to look for assistance, much of which is managed online.

Organizations such as Patient Access Network (PAN), Patient Advocate Foundation (PAF) and HealthWell Foundation can provide supplementary funds for medical treatments, prescriptions and travel expenses.

Most patients do not realize these resources even exist, but are extremely appreciative and relieved when they find at least a portion of the financial burden of their care may be covered.

LIAISON RESPONSIBILITIES

Patients are sometimes admitted to the hospital or seen at facilities other than at their urology office for ancillary treatments.

The nurse navigator can quickly provide the patient and other care centers the medical information needed including medical history, updated medication lists, allergies and other pertinent medical information in order to provide a smooth transition of care.

The same assistance may also be needed when transitioning care at the time of hospital discharge to ensure that the patient is taking the correct medications and has all the appropriate follow-up visits scheduled.

Nurse navigators can help arrange transportation to medical appointments,

Missy Frazier, BSN, RN, is nurse navigator and Dr. John Bishay, MD, is co-director of the Comprehensive Prostate Cancer Clinic at the Urology Center, P.C., in Omaha, Nebraska.

as well as advocate for cancer survivorship programs and arrange referrals.

There are numerous functions in medicine today requiring both advocacy and coordination that are not directly planned by the ordering provider. It's vitally important to ensure patients are successfully progressing along the path set forth by their urologists and as part of their advanced prostate cancer care continuum.

COMPREHENSIVE PROSTATE CANCER CLINIC

Missy Frazier, BSN, RN, was already working as a nurse and caring for prostate cancer patients at The Urology Center, P.C., in Omaha, Nebraska, when our board of directors decided to restructure management of advanced prostate cancer cases.

Just as Florence Nightingale advocated for her patients, the nurse navigator acts in the same role for advanced prostate cancer patients and families.

Under the direction of Dr. John Bishay and Dr. Judson Davies, we developed and implemented our own advanced prostate cancer specialty clinic in April 2019. Frazier was eager to assist and stepped up to the plate as our specialty clinic's nurse navigator.

Her role as nurse navigator means that she is the point of first contact for these patients when they call with questions, concerns, or even just need someone to talk to about the impact of the diagnosis on their day-to-day life.

NAVIGATING THE BUMPY PATH

Our physicians have set forth a path for our patients to follow based on medical expertise and experience, but it is Frazier's role as nurse navigator to walk with them, holding their hand along the way.

It can be a bumpy path for some, especially for patients who do not have the assistance of family or friends. The nurse navigator can advise what bumps to avoid and help make the journey smoother.

Nurse navigators simply do what their name describes – navigate the journey for their patients. They are the experts when it comes to coordinating between care settings, specialties, resources, pharmacies and support groups.

They are also the voice and reassurance many of these patients need on a journey that can be daunting without someone who cares and understands the elements involved.

Just as Florence Nightingale advocated for her patients, the nurse navigator acts in the same role for advanced prostate cancer patients and families. The nurse navigator is there to guide and advocate for them each and every step of the way.

▲ **Anna McGrain**, MSN, ANP-BC, is Nurse Practitioner and Clinical Operations Manager at The Urology Center, P.C., in Omaha, Nebraska..


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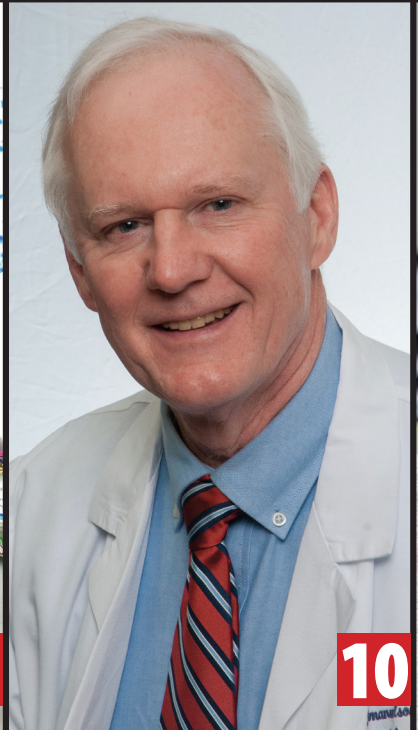
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NURSES
PHYSICIANS
TECHNICIANS
PHARMACISTS
ADMINISTRATORS
FINANCIAL COUNSELORS

WE ARE NCODA

We are 1,500+ cancer care professionals – physicians, nurses, pharmacists, technicians, administrators, financial counselors and more – at 450 practices in 49 states and six countries.

We collaborate with all parties involved in oral chemotherapy – patients, employers, payers, practices, pharmaceutical companies, advocacy groups, professional organizations, PBMs, GPOs, foundations, legislators and state pharmacy boards – to create win-win solutions for all involved.

We believe a patient-centered approach with direct patient access by all members of the medically integrated team is essential for fulfilling patient care, monitoring drug interaction and adherence, obtaining financial assistance, avoiding unnecessary costs, and improving patient education and satisfaction.

We maintain that by working face-to-face with patients, we achieve better treatment outcomes more economically and with less waste than logistics-driven mail order pharmacies that require patients to coordinate their own care through non-local call centers, centralized warehouses and courier delivery services.

We constantly develop initiatives to improve patient care, including a Cost Avoidance and Waste Tracker Tool, a library of Positive Quality Intervention documents, Oral Chemotherapy Education sheets for patients and their caregivers, Treatment Support Kit recommendations, a Financial Assistance database, a Patient Satisfaction Survey and guidance tools for the development and maintenance of Medically Integrated Pharmacies.

We strive to be the world leader in oral oncology by building a patient-centered medically integrated community that ensures every patient receives the maximum benefit from their cancer treatment.

We aspire to provide leadership, expertise, quality standards and sharing of best practices with all of our members.

We are NCODA.

INTRODUCING TWELVE OF NCODA'S MORE THAN 1,500 MEMBERS

1. Jill Jacobs, BA
2. Jorge Garcia, PharmD, MS, MHA, MBA, FACHE
3. Chara Reid, PharmD
4. Natasha Olson, PharmD
5. Carol Hemersbach, CPhT, BSHCA
6. Stacey McCullough, PharmD
7. Ann Roman, MS, ANP-BC, AOCNP
8. Jonathan Heller, MS
9. Mary Anderson, BSN, RN, OCN
10. Richard Emanuelson, MD
11. Patricia Miller, CMA
12. Shanada Monestime, PharmD

JILL JACOBS, BA

TITLE: Medically Integrated Dispensary Manager, Urological Associates PC, Davenport, Iowa.

RESPONSIBILITIES: Manage our practice's dispensary, from processing prescriptions to keeping the dispensary's policies and procedures up to date.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: When I took on the responsibility of our dispensary, I did not know much about filling prescriptions, dealing with prescription insurance or how much of a learning curve it was going to be. I ran with the role and it has been extremely rewarding to know what this service has and can do for our patients.

WHEN DID YOU JOIN NCODA? 2016.

WHY? To network and gain more knowledge and insight in the dispensary area for our practice so the we could effectively provide medications to our patients.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? NCODA has helped our office during our ACHC accreditation process by providing templated policies and standards that were required, discounts on the total cost of accreditation and networking with other practices that had completed accreditation and were willing to assist us with our questions.

JORGE J. GARCIA, PHARMD, MS, MHA, MBA, FACHE

TITLE: Assistant Vice President - System Oncology Pharmacy Service Line, Baptist Health South Florida - Miami Cancer Institute, Miami, Florida.

RESPONSIBILITIES: Systemwide oncology pharmacy services and non-oncology ambulatory pharmacy infusion services.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: I'm not a musician but I am currently doing a national tour presenting my talk, *Biosimilars: Beyond the Scientific Review*. "Concert" stops include the Maryland Society of Health-System Pharmacists, the Florida Southeast Society of Health-System Pharmacists, the ASCO Direct Highlights Miami Symposium, the New Orleans Summer Cancer Symposium, the Florida Society of Clinical Oncology fall meeting and others.

WHEN DID YOU JOIN NCODA? 2016.

WHY? I learned about NCODA in 2016 from colleagues and joined the same year. Oral oncolytics treatment options are growing significantly and these present unique complexities and challenges for patients and providers. NCODA brings healthcare professionals together to develop and disseminate best practices in this space.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? The Cost Avoidance and Waste Tracker Tool is a resource that helps reduce waste associated with high-cost pharmaceuticals. This tool can help patients reduce their out-of-pocket financial burden. This tool can also help self-insured employers reduce cost associated with employee health benefits.

CHARA REID, PHARMD

TITLE: Interim Director of Pharmacy, DuPage Medical Group, Lisle, Illinois.

RESPONSIBILITIES: I am responsible for six oncology infusion centers, two retail pharmacies, one specialty pharmacy and our newest department, the Ambulatory Surgery Center pharmacy team. I lead a team of 13 pharmacists and 16 pharmacy technicians. My primary responsibility is to ensure removal of any barriers for my team to help them care for patients in an efficient and safe manner.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: I think the most unique thing about my career is that I worked at Walgreens for 20 years. I never imagined that leaving my career as a retail pharmacist would land me in oncology. I am so glad that I took that chance on a career change.

WHEN DID YOU JOIN NCODA? 2017.

WHY? I had heard from several account managers that it was a phenomenal organization that focused on oral oncology dispensing. I started my career at DuPage Medical Group in the specialty pharmacy, so I thought I might find some resources to be a better clinician. I attended my first conference in Spring 2018. I was riveted. It was the first time that I attended a conference and I sat on the edge of my seat for lecture after lecture. It was the most informative meeting I ever attended in my pharmacy career. I knew that I had to be a part of it and become more active. I wholeheartedly believed in the mission of passion for patients. Because I believed in that mission, I told every single oncology pharmacist I knew to join. I often speak to different groups of oncology or specialty pharmacists and my common request is that they join NCODA.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? I have used the NCODA resources in multiple ways. I have my pharmacy students use the resources to help guide their patient counseling. I have created oral oncology teaching material for our mid-levels and include NCODA resources. I have documented waste from PBM mismanagement in NCODA's Cost Avoidance and Waste Tracker Tool. I have taken back slide decks from the conferences and shared them with staff. The NCODA resources have been so instrumental in my understanding of oral oncology. I also greatly admire that NCODA is active in helping practices advocate for *going beyond the first fill.*

NATASHA OLSON, PHARMD

TITLE: Oncology Pharmacist, Summit Cancer Centers, Spokane, Washington.

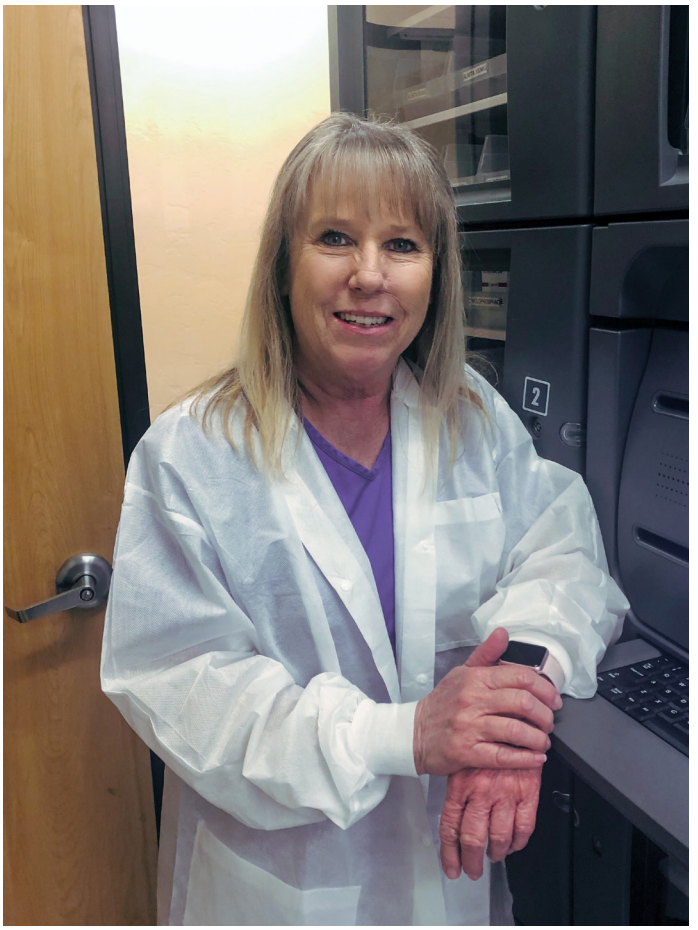
RESPONSIBILITIES: As the only pharmacist for four locations, I am responsible for overseeing our MIP (filling medications, initiation and completion of prior authorizations, finding funding, ordering of medications and maintenance of inventory), management of MIP accounting, counseling on oral medications, maintaining pricing and management of rebates for both oral and IV medications, and chart reviews. I have a great boss who allows me to focus on what is important to me. My goal is a zero dollar co-pay and a 24-hour turnaround on all MIP prescriptions.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: I am passionate about medical mission trips. I have taken seven medical mission trips to Ecuador, working with One Heart Global Ministries. We work to provide quality primary healthcare to the rural people of the Chimborazo province outside of Riobamba.

WHEN DID YOU JOIN NCODA? 2017.

WHY? I joined NCODA just a few months after starting in the practice of oncology. I was recommended to join by another member, Jen O'Doherty. Being in a similar practice setting, she told me she utilized NCODA and its members to ask questions and bounce ideas off others who do the same things we do. This was exactly what I needed! Being new to oncology pharmacy, I felt that I really needed support from others for advice, random questions, and to develop best practices.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? NCODA has greatly helped our practice with the use of Positive Quality Interventions and Oral Chemotherapy Education sheets. These are used daily in our clinics. I have found that patients prefer the formatting of the Oral Chemotherapy Education sheets and find them easier to understand compared to others I have used. I have also found the membership connection to be very helpful. There are a lot of NCODA members that I use for advice and random questions through the NCODA forum and personal connections. My technician and I have gained so much knowledge from NCODA's national meetings. These are great networking opportunities as well as great ways to optimize our MIP.



CAROL HEMERSBACH, CPHT, BSHCA

TITLE: Admixture/IOD technician, Arizona Blood & Cancer Specialists, Tucson, Arizona.

RESPONSIBILITIES: I am responsible for IV admixtures. I will be responsible for setting up our MIP once our providers are ready.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: I have been a pharmacy tech for more than 40 years. When I started in pharmacy we used a typewriter. Pharmacy has changed so much and I am so happy to be part of the oral oncology world. When I started in pharmacy admix, we mixed chemotherapy on the countertops.

WHEN DID YOU JOIN NCODA? 2017.

WHY? I joined because I was introduced to NCODA by Executive Council member Linda Frisk, and felt that this organization could truly help me in my role in the MIP.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? NCODA resources and tools have helped me tremendously. Utilizing NCODA's Patient Satisfaction Survey helped us realize that we were on the right track with patient care. The Positive Quality Intervention documents have helped increase the number of supportive care prescriptions to help with the side effects of oral oncolytics. The support of NCODA has been phenomenal; I know if I have a concern or questions there are numerous experts to call.

STACEY MCCULLOUGH, PHARMD

TITLE: SVP Pharmacy, Tennessee Oncology, PLLC, Nashville, Tennessee.

RESPONSIBILITIES: I am responsible for three terrific teams that make up our pharmacy (Park Pharmacy). Our pharmacy has both URAC and ACHC distinction. Our medically integrated pharmacy team is responsible for EMR regimen builds and content maintenance and oversight for onboarding, training competencies and SOPs for admixture staff.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: A self-assessment may not be most accurate, but as a mom, wife, sister, daughter, friend and colleague, I love to see those around me living their passion and finding joy in each day. Anything I can do to facilitate that makes me happy.

WHEN DID YOU JOIN NCODA? 2016.

WHY? When embarking on the challenge of developing our pharmacy, I was fortunate to have the friendship and insights of terrific people, such as Ray Bailey. I met Mike Reff and knew his passion for patient care. He explained the role that pharmacists have in providing great patient care. In 2016, I copresented with Jim Schwartz, who gave me the hard sell to join NCODA. Having time to participate was a concern, but in reading the website and seeing the list of respected and admired colleagues, I was happy my application was favorably accepted.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? NCODA tools and resources are terrific for continually educating our team and providing resources that we can plug into our processes. But what I love most is the encouragement and challenge of knowing that other pharmacy teams are innovating, integrating and impacting the lives of patients. Seeing these successes and sharing intellect and ideas inspires me to continue to lean in and increase the role, value and outcomes that great pharmacy care can provide.

ANNA ROMAN, MS, ANP-BC, AOCNP

TITLE: Nurse Practitioner, Hematology Oncology Associates of Central New York, Syracuse, New York.

RESPONSIBILITIES: For seven years I managed all of the complex needs of the medical oncology patient. I recently transferred to radiation oncology. The new role has been exciting. I still provide medical management to the oncologic patient with the twist of radiation. Radiation oncology requires me to maintain my knowledge of chemotherapy, as well as drug interactions with radiation.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: I am a repressed artist. My goal is to be able to do art full time. Art fills my life with joy and is a great treasure to share.

WHEN DID YOU JOIN NCODA? 2016.

WHY? I was fortunate enough to be working with two of the founding members of NCODA, so it was a natural progression that I would join. I feel NCODA is setting the industry standard for excellence in serving patients with a diagnosis of cancer.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? NCODA has established reliable guidelines for setting up a new medically integrated pharmacy. They maintain up-to-date resources that are readily available and easy to use.

JONATHAN HELLER, MS

TITLE: Chief Operating Officer, Virginia Cancer Institute, Richmond, Virginia.

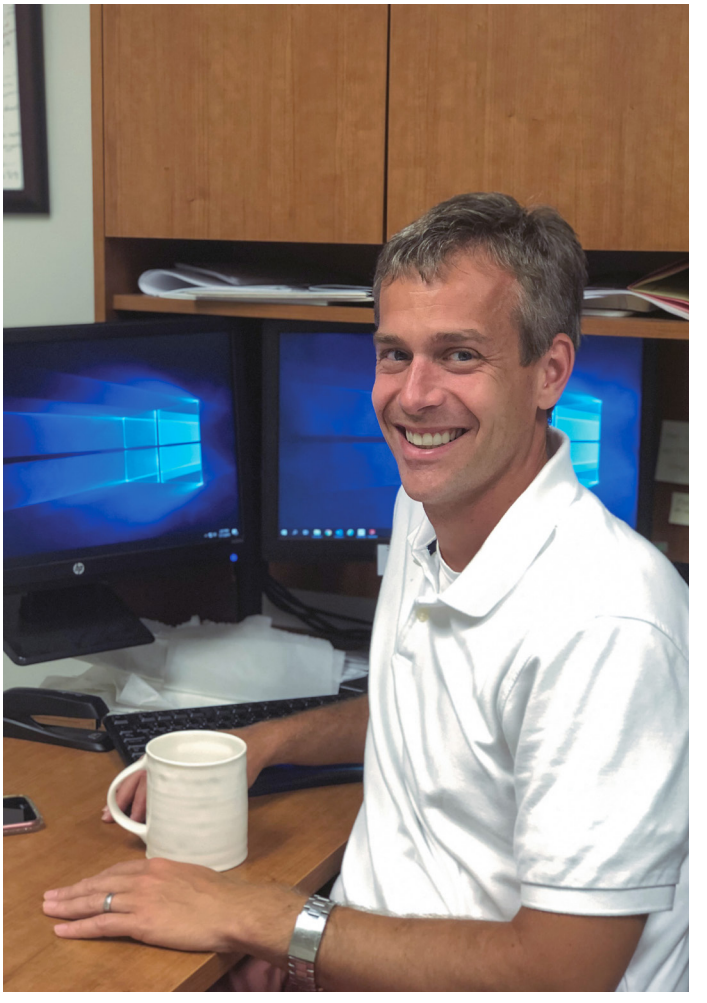
RESPONSIBILITIES: Organization operations: Nursing, Pharmacy, Radiology, Laboratory, Transcription, Outpatient Clinics, Research, Real Estate Management.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: I am an avid runner and the happy father of three kids.

WHEN DID YOU JOIN NCODA? 2018.

WHY? I was new to the outpatient oral pharmacy environment and I wanted to learn more. NCODA was able to assist me in networking with my peers to gain some valuable knowledge about oncology medically integrated pharmacies.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? Recently we started the payor credentialing and accreditation process. I reached out to NCODA to learn more about the requirements from others who had completed these items. NCODA not only had a collection of materials available for review, but they were able to provide some key contacts that enabled me to network with others about the credentialing and accreditation process.



MARY ANDERSON, BSN, RN, OCN

TITLE: Oral Oncolytic Nurse Navigator, Norton Cancer Institute, Louisville, Kentucky.

RESPONSIBILITIES: I oversee the nursing oral oncolytic process, which I codeveloped in partnership with nursing leadership and a physician champion. I track oral chemotherapy patients and their prescriptions though ordering and acquisition, patient education, monitoring and follow-up. I collaborate with the in-house specialty pharmacy, financial counselors and nurse clinicians to promote patient safety and provider satisfaction through timely acquisition and interdisciplinary patient support.

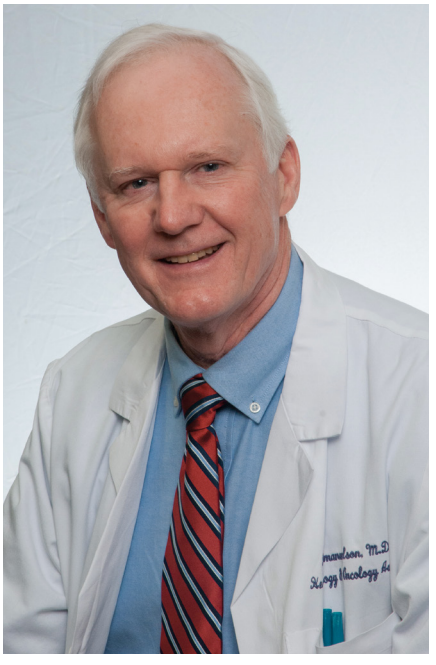
TELL US SOMETHING UNIQUE ABOUT YOURSELF: I have six sisters who are my best friends. I enjoy following the University of Kentucky Wildcats, gardening and home decorating. I love to paint and have painted every room in my house at least three times!

WHEN DID YOU JOIN NCODA? 2016.

WHY? I joined NCODA when a mutual acquaintance introduced me to NCODA Executive Director Michael Reff. As a nurse taking on a newly developed role, I was eager to learn best practices from others with a passion for optimizing outcomes in patients taking oral oncolytics.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? Multiple NCODA initiatives have provided value to my daily practice by helping to alleviate common barriers when caring for patients taking oral oncolytics. The Oral Chemotherapy Education (OCE) sheets are very popular with my nurse colleagues and are a great resource for patient education as they cover not only side effect management strategies, but also provide detailed, easy-to-understand information on safe handling and proper disposal. The Positive Quality Intervention documents are a great resource for incorporating evidenced base practice into patient monitoring and follow-up care. The NCODA Nursing Committee has exceeded my expectations. I have really enjoyed sharing what I have learned through the years with nurses from other oncology practices. In addition to developing various tools to assist nurses in their daily practice, we have forged new friendships as well!

I joined concomitant with the development and opening of our medically integrated pharmacy of self-administered oncology & hematology medications to gain access to the expertise of NCODA and its member practices.



RICHARD EMANUELSON, MD

TITLE: Medical Director, Hematology Oncology Associates of Northeastern Pennsylvania, PC, Dunmore, Pennsylvania.

RESPONSIBILITIES: I monitor national guideline compliance of practicing providers in our group, assist the billing department with reimbursement issues, provide clinical input in practice policies developed, provide clinical input on practice decisions on product use that will impact patients and the practice financially, and research/contact local and national affiliations that may be available to our independent private subspecialty practice.

WHEN DID YOU JOIN NCODA? 2018.

WHY? I joined concomitant with the development and opening of our medically integrated pharmacy of self-administered oncology and hematology medications to gain access to the expertise of NCODA and its member practices.

PATRICIA MILLER, CMA

TITLE: Financial Counselor, Lancaster Cancer Center, Lancaster, Pennsylvania.

RESPONSIBILITIES: I verify patient insurance benefits, determine costs and get assistance if needed for the patient.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: I have a very outgoing personality and try to make every patient smile. I sing and dance sometimes. I try to go above and beyond for every patient. I know they are going through a lot and I just want to make their journey as easy as possible. If I can relieve their financial burden, that's a plus.

WHEN DID YOU JOIN NCODA? 2018.

WHY? I have been at several different meetings that mentioned NCODA and decided to join as another resource to help in obtaining patient assistance for our patients.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? I have used the NCODA Financial Assistance resource to look up drugs to obtain patient assistance. The NCODA website has a wealth of information about each drug, which has been helpful in patient education.

SHANADA MONESTIME, PHARMD

TITLE: Assistant Professor, Hematology/Oncology/Transplant, University of North Texas Health Science Center/ Center for Cancer and Blood Disorders, Fort Worth, Texas.

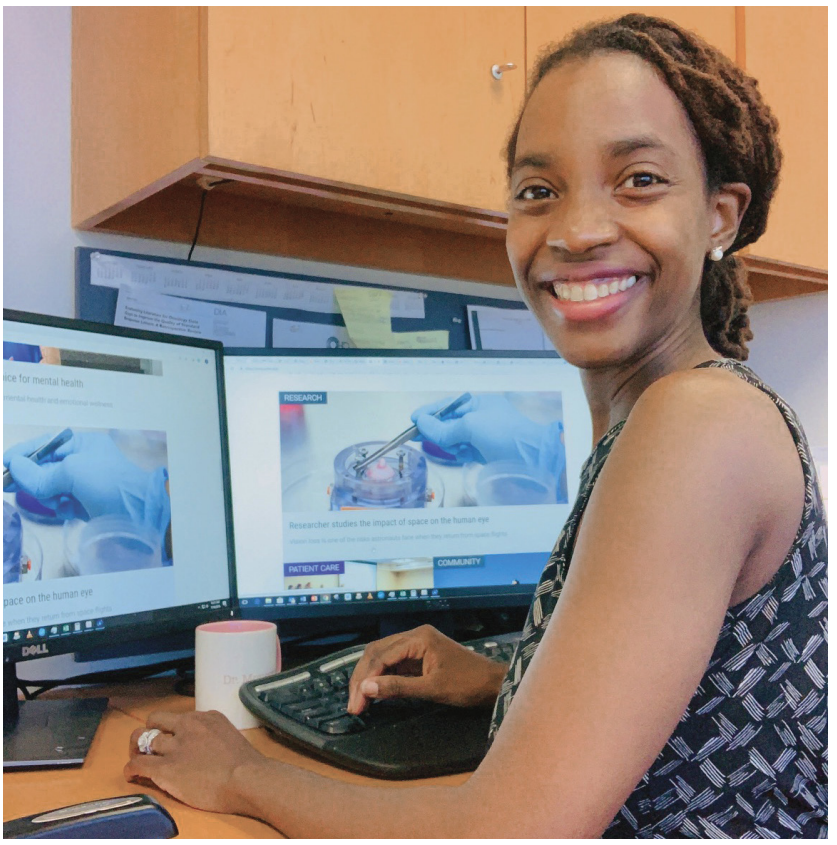
RESPONSIBILITIES: As a clinical faculty member, I am inspired to serve disadvantaged patient populations through clinical applications and research. I currently find avenues to increase access to care, improve patient-provider relationships, advocate for patients to receive optimal care, identify resources for patients to afford chemotherapy through patient assistance programs, and conduct scholastic research in the field of cancer health disparities. My overarching research focuses on evaluating safety and efficacy of antineoplastic agents in special populations (i.e., obesity) and minority populations. I also serve as the faculty advisor for the NCODA Professional Student Organization chapter at the University of North Texas Health Science Center.

TELL US SOMETHING UNIQUE ABOUT YOURSELF: I was recently selected to serve as a scholar for the Obesity Health Disparities PRIDE program, to conduct research within my area of interest.

WHEN DID YOU JOIN NCODA? 2019.

WHY? Two pharmacy students were interested in starting an NCODA Professional Student Organization chapter on campus and asked if I would serve as the advisor. This appointment has been pivotal because it allowed me to introduce oncology to our students prior to their third year, mentor students interested in research to present at NCODA meetings and provided me with educational resources and tools to use in the classroom setting.

HOW HAVE NCODA RESOURCES, TOOLS OR STANDARDS AND PRACTICES HELPED YOU AND YOUR PRACTICE? I have used the Oral Chemotherapy Education sheets to train students on how to counsel patients who may experience common side effects from their oral chemotherapy.



HARNESS THE POWER OF STIVARGA® (regorafenib)

Proven efficacy helps to maximize overall survival (OS) potential for your patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if *RAS* wild-type, an anti-EGFR therapy[1]

Indication

STIVARGA® (regorafenib) is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if *RAS* wild-type, an anti-EGFR therapy.

Important Safety Information

WARNING: HEPATOTOXICITY

- **Severe and sometimes fatal hepatotoxicity has occurred in clinical trials.**
- **Monitor hepatic function prior to and during treatment.**
- **Interrupt and then reduce or discontinue STIVARGA for hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis, depending upon severity and persistence.**

Hepatotoxicity: Severe drug-induced liver injury with fatal outcome occurred in STIVARGA-treated patients across all clinical trials. In most cases, liver dysfunction occurred within the first 2 months of therapy and was characterized by a hepatocellular pattern of injury. In metastatic colorectal cancer (mCRC), fatal hepatic failure occurred in 1.6% of patients in the STIVARGA arm and in 0.4% of patients in the placebo arm.

Liver Function Monitoring: Obtain liver function tests (ALT, AST, and bilirubin) before initiation of STIVARGA and monitor at least every 2 weeks during the first 2 months of treatment. Thereafter, monitor monthly or more frequently as clinically indicated. Monitor liver function tests weekly in patients experiencing elevated liver function tests until improvement to less than 3 times the upper limit of normal (ULN) or baseline values. Temporarily hold and then reduce or permanently discontinue STIVARGA, depending on the severity and persistence of hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis.

Infections: STIVARGA caused an increased risk of infections. The overall incidence of infection (Grades 1-5) was higher (32% vs 17%) in 1142 STIVARGA-treated patients as compared to the control arm in randomized placebo-controlled trials. The incidence of grade 3 or greater infections in STIVARGA-treated patients was 9%. The most common infections were urinary tract infections (5.7%), nasopharyngitis (4.0%), mucocutaneous and systemic fungal infections (3.3%) and pneumonia (2.6%). Fatal outcomes caused by infection occurred more often in patients treated with STIVARGA (1.0%) as compared to patients receiving placebo (0.3%); the most common fatal infections were respiratory (0.6% vs 0.2%). Withhold STIVARGA for Grade 3 or 4 infections, or worsening infection of any grade. Resume STIVARGA at the same dose following resolution of infection.

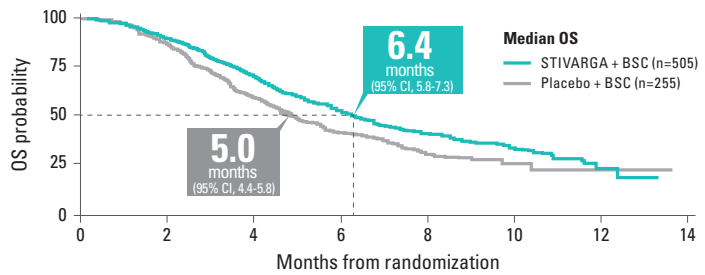
Hemorrhage: STIVARGA caused an increased incidence of hemorrhage. The overall incidence (Grades 1-5) was 18.2% in 1142 patients treated with STIVARGA vs 9.5% with placebo in randomized, placebo-controlled trials. The incidence of grade 3 or greater hemorrhage in patients treated with STIVARGA was 3.0%. The incidence of fatal hemorrhagic events was 0.7%, involving the central nervous system or the respiratory, gastrointestinal, or genitourinary tracts. Permanently discontinue STIVARGA in patients with severe or life-threatening hemorrhage and monitor INR levels more frequently in patients receiving warfarin.

Gastrointestinal Perforation or Fistula: Gastrointestinal perforation occurred in 0.6% of 4518 patients treated with STIVARGA across all clinical trials of STIVARGA administered as a single agent; this included eight fatal events. Gastrointestinal fistula occurred in 0.8% of patients treated with STIVARGA and in 0.2% of patients in the placebo arm across randomized, placebo-controlled trials. Permanently discontinue STIVARGA in patients who develop gastrointestinal perforation or fistula.

Dermatological Toxicity: In randomized, placebo-controlled trials, adverse skin reactions occurred in 71.9% of patients with STIVARGA arm and 25.5% of patients in the placebo arm including hand-foot skin reaction (HFSR) also known as palmar-plantar erythrodysesthesia syndrome (PPES) and severe rash, requiring dose modification. In the randomized, placebo-controlled trials, the overall incidence of HFSR was higher in 1142 STIVARGA-treated patients (53% vs 8%) than in the placebo-treated patients. Most cases of HFSR in STIVARGA-treated patients appeared during the first cycle of treatment. The incidences of Grade 3 HFSR (16%

Harness the proven efficacy of STIVARGA to help maximize OS potential for your previously treated patients with mCRC[1]

Significant improvement in OS[1]*



Patients at risk, n						
STIVARGA + BSC	452	352	187	93	33	7
Placebo + BSC	221	150	75	32	9	3

23%
reduction in risk of death with STIVARGA[1]
HR: 0.77
(95% CI, 0.64-0.94)
P=0.0102

- STIVARGA improved OS in CORRECT, which included patients with historically collected *KRAS* status (N=729)[1]
  - Historical *KRAS* status was assessed (59% mutant, 41% wild-type *KRAS*)
- There were 275 deaths out of 505 patients treated with STIVARGA (55%) vs 157 deaths out of 255 patients treated with placebo (62%)[1]

*OS was the primary endpoint of CORRECT.[1]
CORRECT (COloRectal cancer treated with REgorafenib or plaCebo after failure of standard Therapy) was a large, international, placebo-controlled, double-blind, randomized (2:1), phase III trial that evaluated the efficacy and safety of STIVARGA in patients with mCRC who had progressed after all approved standard therapies (N=760).[1]
BSC, best supportive care; CI, confidence interval; HR, hazard ratio.

In CORRECT, patients were able to receive cytotoxic therapy following treatment with STIVARGA[2]

CORRECT trial: 26% of patients received cytotoxic therapy after STIVARGA[2,3]

Systemic anticancer treatment during CORRECT trial follow-up	**STIVARGA, n (%)** (n=505)	**Placebo, n (%)** (n=255)
Patients with ≥1 medication	131 (26)	76 (30)
Any antineoplastic or immunomodulation agent	130 (26)	74 (29)

vs <1%), Grade 3 rash (3% vs <1%), serious adverse reactions of erythema multiforme (<0.1% vs 0%), and Stevens-Johnson syndrome (<0.1% vs 0%) were higher in STIVARGA-treated patients. Across all trials, a higher incidence of HFSR was observed in Asian patients treated with STIVARGA (all grades: 72%; Grade 3: 18%). Toxic epidermal necrolysis occurred in 0.02% of 4518 STIVARGA-treated patients across all clinical trials of STIVARGA administered as a single agent. Withhold STIVARGA, reduce the dose, or permanently discontinue depending on the severity and persistence of dermatologic toxicity.

Hypertension: Hypertensive crisis occurred in 0.2% in STIVARGA-treated patients and in none of the patients in placebo arm across all randomized, placebo-controlled trials. STIVARGA caused an increased incidence of hypertension (30% vs 8% in mCRC). The onset of hypertension occurred during the first cycle of treatment in most patients who developed hypertension (67% in randomized, placebo controlled trials). Do not initiate STIVARGA until blood pressure is adequately controlled. Monitor blood pressure weekly for the first 6 weeks of treatment and then every cycle, or more frequently, as clinically indicated. Temporarily or permanently withhold STIVARGA for severe or uncontrolled hypertension.

Cardiac Ischemia and Infarction: STIVARGA increased the incidence of myocardial ischemia and infarction (0.9% with STIVARGA vs 0.2% with placebo) in randomized placebo-controlled trials. Withhold STIVARGA in patients who develop new or acute cardiac ischemia or infarction, and resume only after resolution of acute cardiac ischemic events if the potential benefits outweigh the risks of further cardiac ischemia.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Reversible posterior leukoencephalopathy syndrome (RPLS), a syndrome of subcortical vasogenic edema diagnosed by characteristics finding on MRI, occurred in one of 4800 STIVARGA-treated patients across all clinical trials. Perform an evaluation for RPLS in any patient presenting with seizures, severe headache, visual disturbances, confusion, or altered mental function. Discontinue STIVARGA in patients who develop RPLS.

Wound Healing Complications: Treatment with STIVARGA should be stopped at least 2 weeks prior to scheduled surgery. Resuming treatment after surgery should be based on clinical judgment of adequate wound healing. STIVARGA should be discontinued in patients with wound dehiscence.

Embryo-Fetal Toxicity: STIVARGA can cause fetal harm when administered to a pregnant woman. There are no available data on STIVARGA use in pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with STIVARGA and for 2 months after the final dose.

Nursing Mothers: Because of the potential for serious adverse reactions in breastfed infants from STIVARGA, do not breastfeed during treatment with STIVARGA and for 2 weeks after the final dose.

Most Frequently Observed Adverse Drug Reactions in mCRC (≥30%): The most frequently observed adverse drug reactions (≥30%) in STIVARGA-treated patients vs placebo-treated patients in mCRC, respectively, were: asthenia/fatigue (64% vs 46%), pain (59% vs 48%), decreased appetite and food intake (47% vs 28%), HFSR/PPE (45% vs 7%), diarrhea (43% vs 17%), mucositis (33% vs 5%), weight loss (32% vs 10%), infection (31% vs 17%), hypertension (30% vs 8%), and dysphonia (30% vs 6%).

Please see brief summary of full Prescribing Information, including the Boxed Warning, on the following pages.

References: 1. STIVARGA Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; June 2018. **2.** Grothey A, Van Cutsem E, Sobrero A, et al; CORRECT Study Group. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet.* 2013;381(9863):303-312. **3.** Grothey A, Van Cutsem E, Sobrero A, et al; CORRECT Study Group. Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial [supplement published online November 22, 2012]. *Lancet.* http://dx.doi.org/10.1016/S0140-6736(12)61900-X.

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Stivarga®
(regorafenib) tablets

STIVARGA® (regorafenib) tablets, for oral use
Initial U.S. Approval: 2012

BRIEF SUMMARY OF PRESCRIBING INFORMATION
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

WARNING: HEPATOTOXICITY

- **Severe and sometimes fatal hepatotoxicity has occurred in clinical trials *[see Warnings and Precautions (5.1)]*.**
- **Monitor hepatic function prior to and during treatment *[see Warnings and Precautions (5.1)]*.**
- **Interrupt and then reduce or discontinue STIVARGA for hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis, depending upon severity and persistence *[see Dosage and Administration (2.2)]*.**

1 INDICATIONS AND USAGE

1.1 Colorectal Cancer

STIVARGA is indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type, an anti-EGFR therapy.

1.2 Gastrointestinal Stromal Tumors

STIVARGA is indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.

1.3 Hepatocellular Carcinoma

STIVARGA is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hepatotoxicity

Severe drug-induced liver injury with fatal outcome occurred in STIVARGA-treated patients in clinical trials. In most cases, liver dysfunction occurred within the first 2 months of therapy and was characterized by a hepatocellular pattern of injury.

In the CORRECT study, fatal hepatic failure occurred in 1.6% of patients in the regorafenib arm and in 0.4% of patients in the placebo arm. In the GRID study, fatal hepatic failure occurred in 0.8% of patients in the regorafenib arm. In the RESORCE study, there was no increase in the incidence of fatal hepatic failure as compared to placebo *[see Adverse Reactions (6.1)]*.

Obtain liver function tests (ALT, AST, and bilirubin) before initiation of STIVARGA and monitor at least every two weeks during the first 2 months of treatment. Thereafter, monitor monthly or more frequently as clinically indicated. Monitor liver function tests weekly in patients experiencing elevated liver function tests until improvement to less than 3 times the ULN or baseline.

Temporarily hold and then reduce or permanently discontinue STIVARGA depending on the severity and persistence of hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis *[see Dosage and Administration (2.2) and Use in Specific Populations (8.6)]*.

5.2 Infections

STIVARGA caused an increased risk of infections. The overall incidence of infection (Grades 1-5) was higher (32% vs. 17%) in 1142 STIVARGA-treated patients as compared to the control arm in randomized placebo-controlled trials. The incidence of grade 3 or greater infections in STIVARGA treated patients was 9%. The most common infections were urinary tract infections (5.7%), nasopharyngitis (4.0%), mucocutaneous and systemic fungal infections (3.3%) and pneumonia (2.6%). Fatal outcomes caused by infection occurred more often in patients treated with STIVARGA (1.0%) as compared to patients receiving placebo (0.3%); the most common fatal infections were respiratory (0.6% in STIVARGA-treated patients vs 0.2% in patients receiving placebo).

Withhold STIVARGA for Grade 3 or 4 infections, or worsening infection of any grade. Resume STIVARGA at the same dose following resolution of infection *[see Dosage and Administration (2.2)]*.

5.3 Hemorrhage

STIVARGA caused an increased incidence of hemorrhage. The overall incidence (Grades 1-5) was 18.2% in 1142 patients treated with STIVARGA and 9.5% in patients receiving placebo in randomized, placebo-controlled trials. The incidence of grade 3 or greater hemorrhage in patients treated with STIVARGA was 3.0%. The incidence of fatal hemorrhagic events was 0.7%, involving the central nervous system or the respiratory, gastrointestinal, or genitourinary tracts.

Permanently discontinue STIVARGA in patients with severe or life-threatening hemorrhage. Monitor INR levels more frequently in patients receiving warfarin *[see Clinical Pharmacology (12.3)]*.

5.4 Gastrointestinal Perforation or Fistula

Gastrointestinal perforation occurred in 0.6% of 4518 patients treated with STIVARGA across all clinical trials of STIVARGA administered as a single agent; this included eight fatal events.

Gastrointestinal fistula occurred in 0.8% of patients treated with STIVARGA and 0.2% of patients in placebo arm across randomized, placebo-controlled trials. Permanently discontinue STIVARGA in patients who develop gastrointestinal perforation or fistula.

5.5 Dermatologic Toxicity

In randomized, placebo-controlled trials, adverse skin reactions occurred in 71.9% of patients in the regorafenib arm and in 25.5% of patients in the placebo arm, including hand-foot skin reaction (HFSR) also known as palmar-plantar erythrodysesthesia syndrome (PPES), and severe rash requiring dose modification.

In the randomized, placebo-controlled trials, the overall incidence of HFSR was higher in 1142 STIVARGA-treated patients (53%) than in the placebo-treated patients (8%). Most cases of HFSR in STIVARGA-treated patients appeared during the first cycle of treatment. The incidences of Grade 3 HFSR (16% versus <1%), Grade 3 rash (3% versus <1%), serious adverse reactions of erythema multiforme (<0.1% vs. 0%) and Stevens-Johnson Syndrome (<0.1% vs. 0%) were also higher in STIVARGA-treated patients *[see Adverse Reactions (6.1)]*. Across all trials, a higher incidence of HFSR was observed in Asian patients treated with STIVARGA (all grades: 72%; Grade 3: 18%) *[see Use in Specific Populations (8.8)]*.

Toxic epidermal necrolysis occurred in 0.02% of 4518 STIVARGA-treated patients across all clinical trials of STIVARGA administered as a single agent.

Withhold STIVARGA, reduce the dose, or permanently discontinue STIVARGA depending on the severity and persistence of dermatologic toxicity *[see Dosage and Administration (2.2)]*. Institute supportive measures for symptomatic relief.

5.6 Hypertension

In randomized, placebo-controlled trials, hypertensive crisis occurred in 0.2% of patients in the regorafenib arms and in none of the patients in the placebo arms. STIVARGA caused an increased incidence of hypertension (30% versus 8% in CORRECT, 59% versus 27% in GRID, and 31% versus 6% in RESORCE) *[see Adverse Reactions (6.1)]*. The onset of hypertension occurred during the first cycle of treatment in most patients who developed hypertension (67% in randomized, placebo-controlled trials).

Do not initiate STIVARGA unless blood pressure is adequately controlled. Monitor blood pressure weekly for the first 6 weeks of treatment and then every cycle, or more frequently, as clinically indicated. Temporarily or permanently withhold STIVARGA for severe or uncontrolled hypertension *[see Dosage and Administration (2.2)]*.

5.7 Cardiac Ischemia and Infarction

STIVARGA increased the incidence of myocardial ischemia and infarction (0.9% vs 0.2%) in randomized placebo-controlled trials *[see Adverse Reactions (6.1)]*. Withhold STIVARGA in patients who develop new or acute onset cardiac ischemia or infarction. Resume STIVARGA only after resolution of acute cardiac ischemic events, if the potential benefits outweigh the risks of further cardiac ischemia.

5.8 Reversible Posterior Leukoencephalopathy Syndrome

Reversible posterior leukoencephalopathy syndrome (RPLS), a syndrome of subcortical vasogenic edema diagnosed by characteristic finding on MRI, occurred in one of 4800 STIVARGA-treated patients across all clinical trials. Perform an evaluation for RPLS in any patient presenting with seizures, severe headache, visual disturbances, confusion or altered mental function. Discontinue STIVARGA in patients who develop RPLS.

5.9 Wound Healing Complications

No formal studies of the effect of regorafenib on wound healing have been conducted. Since vascular endothelial growth factor receptor (VEGFR) inhibitors such as STIVARGA can impair wound healing, discontinue treatment with STIVARGA at least 2 weeks prior to scheduled surgery. The decision to resume STIVARGA after surgery should be based on clinical judgment of adequate wound healing. Discontinue STIVARGA in patients with wound dehiscence.

5.10 Embryo-Fetal Toxicity

Based on animal studies and its mechanism of action, STIVARGA can cause fetal harm when administered to a pregnant woman. There are no available data on STIVARGA use in pregnant women. Regorafenib was embryolethal and teratogenic in rats and rabbits at exposures lower than human exposures at the recommended dose, with increased incidences of cardiovascular, genitourinary, and skeletal malformations. Advise pregnant women of the potential risk to a fetus.

Advise females of reproductive potential to use effective contraception during treatment with STIVARGA and for 2 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with STIVARGA and for 2 months after the final dose *[see Use in Specific Populations (8.1), (8.3)]*.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed elsewhere in the labeling:

- Hepatotoxicity *[see Warnings and Precautions (5.1)]*
- Infections *[see Warnings and Precautions (5.2)]*
- Hemorrhage *[see Warnings and Precautions (5.3)]*
- Gastrointestinal Perforation or Fistula *[see Warnings and Precautions (5.4)]*
- Dermatological Toxicity *[see Warnings and Precautions (5.5)]*
- Hypertension *[see Warnings and Precautions (5.6)]*
- Cardiac Ischemia and Infarction *[see Warnings and Precautions (5.7)]*
- Reversible Posterior Leukoencephalopathy Syndrome (RPLS) *[see Warnings and Precautions (5.8)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rate observed in practice.

The data described in the WARNINGS AND PRECAUTIONS section reflect exposure to STIVARGA in more than 4800 patients who were enrolled in four randomized, placebo-controlled trials (n=1142), an expanded access program (CONSIGN, n=2864), or single arm clinical trials (single agent or in combination with other agents). There were 4518 patients who received STIVARGA as a single agent; the distribution of underlying malignancies was 80% CRC, 4% GIST, 10% HCC, 6% other solid tumors; and 74% were White, 11% Asian, and 15% race not known. Among these 4518 patients, 83% received STIVARGA for at least 21 days and 20% received STIVARGA for 6 months or longer.

In randomized placebo-controlled trials (CORRECT, GRID, RESORCE and CONCUR), the most frequently observed adverse drug reactions (≥20%) in patients receiving STIVARGA are pain (including gastrointestinal and abdominal pain), HFSR, asthenia/fatigue, diarrhea, decreased appetite/food intake, hypertension, infection, dysphonia, hyperbilirubinemia, fever, mucositis, weight loss, rash, and nausea.

Colorectal Cancer

The safety data described below, except where noted, are derived from a randomized (2:1), double-blind, placebo-controlled trial (CORRECT) in which 500 patients (median age 61 years; 61% men) with previously-treated metastatic colorectal cancer (CRC) received STIVARGA as a single agent at the dose of 160 mg daily for the first 3 weeks of each 4 week treatment cycle and 253 patients (median age 61 years; 60% men) received placebo. The median duration of therapy was 1.7 months (range 2 days, 10.8 months) for patients receiving STIVARGA. Due to adverse reactions, 61% of the patients receiving STIVARGA required a dose interruption and 38% of the patients had their dose reduced. Adverse reactions that resulted in treatment discontinuation occurred in 8.2% of STIVARGA-treated patients compared to 1.2% of patients who received placebo. Hand-foot skin reaction (HFSR) and rash were the most common reasons for permanent discontinuation of STIVARGA.

Table 1 provides the incidence of adverse reactions (≥10%) in patients in CORRECT.

Table 1: Adverse drug reactions reported in ≥10% of patients treated with STIVARGA in CORRECT and reported more commonly than in patients receiving placebo[a]

Adverse Reactions	STIVARGA (N=500)		Placebo (N=253)	
	Grade		Grade	
	All %	≥ 3 %	All %	≥ 3 %
General disorders and administration site conditions				
Asthenia/fatigue	64	15	46	9
Pain	59	9	48	7
Fever	28	2	15	0
Metabolism and nutrition disorders				
Decreased appetite and food intake	47	5	28	4
Skin and subcutaneous tissue disorders				
HFSR/PPES	45	17	7	0
Rash [b]	26	6	4	<1
Gastrointestinal disorders				
Diarrhea	43	8	17	2
Mucositis	33	4	5	0
Investigations				
Weight loss	32	<1	10	0
Infections and infestations				
Infection [c]	31	9	17	6
Vascular disorders				
Hypertension	30	8	8	<1
Hemorrhage [c]	21	2	8	<1
Respiratory, thoracic and mediastinal disorders				
Dysphonia	30	0	6	0
Nervous system disorders				
Headache	10	<1	7	0

[a] Adverse reactions graded according to National Cancer Institute Common Toxicity for Adverse Events version 3.0 (NCI CTCAE v3.0).
[b] The term rash represents reports of events of drug eruption, rash, erythematous rash, generalized rash, macular rash, maculo-papular rash, papular rash, and pruritic rash.
[c] Fatal outcomes observed.

Table 2 provides laboratory abnormalities observed in CORRECT.

Table 2: Laboratory test abnormalities reported in CORRECT

Laboratory Parameter	STIVARGA (N=500 [a])			Placebo (N=253 [a])		
	Grade [b]			Grade [b]		
	All %	3 %	4 %	All %	3 %	4 %
Blood and lymphatic system disorders						
Anemia	79	5	1	66	3	0
Thrombocytopenia	41	2	<1	17	<1	0
Neutropenia	3	1	0	0	0	0
Lymphopenia	54	9	0	35	4	<1
Metabolism and nutrition disorders						
Hypocalcemia	59	1	<1	18	1	0
Hypokalemia	26	4	0	8	<1	0
Hyponatremia	30	7	1	22	4	0
Hypophosphatemia	57	31	1	11	4	0
Hepatobiliary disorders						
Hyperbilirubinemia	45	10	3	17	5	3
Increased AST	65	5	1	46	4	1
Increased ALT	45	5	1	30	3	<1
Renal and urinary disorders						
Proteinuria[c]	84	2	0	61	1	0

Table 2 continued at top of next column

Laboratory Parameter	STIVARGA (N=500 [a])			Placebo (N=253 [a])		
	Grade [b]			Grade [b]		
	All %	3 %	4 %	All %	3 %	4 %
Investigations						
Increased INR[d]	24	4	N/A	17	2	N/A
Increased Lipase	46	9	2	19	3	2
Increased Amylase	26	2	<1	17	2	<1

[a] % based on number of patients with post-baseline samples which may be less than 500 (regorafenib) or 253 (placebo).
[b] NCI CTCAE v3.0.
[c] Based on urine protein-creatinine ratio data.
[d] International normalized ratio: No Grade 4 denoted in NCI CTCAE, v3.0.

Gastrointestinal Stromal Tumors

The safety data described below are derived from a randomized (2:1), double-blind, placebo-controlled trial (GRID) in which 132 patients (median age 60 years; 64% men) with previously-treated GIST received STIVARGA as a single agent at a dose of 160 mg daily for the first 3 weeks of each 4 week treatment cycle and 66 patients (median age 61 years; 64% men) received placebo. The median duration of therapy was 5.7 months (range 1 day, 11.7 months) for patients receiving STIVARGA. Dose interruptions for adverse events were required in 58% of patients receiving STIVARGA and 50% of patients had their dose reduced. Adverse reactions that resulted in treatment discontinuation were reported in 2.3% of STIVARGA-treated patients compared to 1.5% of patients who received placebo.

Table 3 provides the incidence of adverse reactions (≥10%) in patients in GRID.

Table 3: Adverse reactions reported in ≥10% patients treated with STIVARGA in GRID and reported more commonly than in patients receiving placebo[a]

Adverse Reactions	STIVARGA (N=132)		Placebo (N=66)	
	Grade		Grade	
	All %	≥ 3 %	All %	≥ 3 %
Skin and subcutaneous tissue disorders				
HFSR/PPE	67	22	12	2
Rash [b]	30	7	3	0
Alopecia	24	2	2	0
General disorders and administration site conditions	52	4	39	2
Asthenia/Fatigue	21	0	11	2
Fever				
Vascular disorders				
Hypertension	59	28	27	5
Hemorrhage	11	4	3	0
Gastrointestinal disorders				
Pain	60	8	55	14
Diarrhea	47	8	9	0
Mucositis	40	2	8	2
Nausea	20	2	12	2
Vomiting	17	<1	8	0
Respiratory, thoracic and mediastinal disorders				
Dysphonia	39	0	9	0
Infections and infestations				
Infection [c]	32	5	5	0
Metabolism and nutrition disorders				
Decreased appetite and food intake	31	<1	21	3
Hypothyroidism [d]	18	0	6	0
Nervous system disorders				
Headache	16	0	9	0
Investigations				
Weight loss	14	0	8	0
Musculoskeletal and connective tissue disorders				
Muscle spasms	14	0	3	0

[a] Adverse reactions graded according to NCI CTCAE v4.0.
[b] The term rash represents reports of events of rash, erythematous rash, macular rash, maculo-papular rash, papular rash and pruritic rash.
[c] Fatal outcomes observed.
[d] Hypothyroidism incidence based on subset of patients with normal TSH and no thyroid supplementation at baseline.

Table 4 provides laboratory abnormalities observed in GRID.

Table 4: Laboratory test abnormalities reported in GRID

Laboratory Parameter	STIVARGA (N=132 [a])			Placebo (N=66 [a])		
	Grade [b]			Grade [b]		
	All %	3 %	4 %	All %	3 %	4 %
Blood and lymphatic system disorders						
Thrombocytopenia	13	1	0	2	0	2
Neutropenia	16	2	1	12	3	0
Lymphopenia	30	8	0	24	3	0

Table 4 continued at top of next column

Laboratory Parameter	STIVARGA (N=132 [a])			Placebo (N=66 [a])		
	Grade [b]			Grade [b]		
	All %	3 %	4 %	All %	3 %	4 %
Metabolism and nutrition disorders						
Hypocalcemia	17	2	0	5	0	0
Hypokalemia	21	3	0	3	0	0
Hypophosphatemia	55	20	2	3	2	0
Hepatobiliary disorders						
Hyperbilirubinemia	33	3	1	12	2	0
Increased AST	58	3	1	47	3	0
Increased ALT	39	4	1	39	2	0
Renal and urinary disorders						
Proteinuria [c]	59	3	- [d]	53	3	- [d]
Investigations						
Increased Lipase	14	0	1	5	0	0

[a] Percent based on number of patients with post-baseline samples which may be less than 132 (regorafenib) or 66 (placebo).
[b] NCI CTCAE v4.0.
[c] Based on urine protein-creatinine ratio data.
[d] No Grade 4 denoted in NCI CTCAE v4.0.

Hepatocellular Carcinoma

The safety data described below are derived from a randomized (2:1), double-blind, placebo-controlled trial (RESORCE) in which patients with previously-treated HCC received either STIVARGA (n=374) 160 mg orally on days 1-21 of each 4 week treatment cycle or placebo (n=193). The median age was 63 years, 88% were men, 98% had Child-Pugh A cirrhosis, 66% had an ECOG performance status (PS) of 0 and 34% had PS of 1. The median duration of therapy was 3.5 months (range 1 day to 29.4 months) for patients receiving STIVARGA. Of the patients receiving STIVARGA, 33% were exposed to STIVARGA for greater than or equal to 6 months and 14% were exposed to STIVARGA for greater than or equal to 12 months. Dose interruptions for adverse events were required in 58.3% of patients receiving STIVARGA and 48% of patients had their dose reduced. The most common adverse reactions requiring dose modification (interruption or dose reduction) were HFSR/PPES (20.6%), blood bilirubin increase (5.9%), fatigue (5.1%) and diarrhea (5.3%). Adverse reactions that resulted in treatment discontinuation were reported in 10.4% of STIVARGA-treated patients compared to 3.6% of patients who received placebo; the most common adverse reactions requiring discontinuation of STIVARGA were HFSR/PPES (1.9%) and AST increased (1.6%).

Table 5 provides the incidence of adverse reactions (≥10%) in patients in RESORCE.

Table 5: Adverse reactions reported in ≥10% of patients treated with STIVARGA in RESORCE and reported more commonly than in patients receiving placebo[a]

Adverse Reactions	STIVARGA (N=374)		Placebo (N=193)	
	Grade		Grade	
	All %	≥ 3 %	All %	≥ 3 %
Skin and subcutaneous tissue disorders				
HFSR/PPE	51	12	7	<1
General disorders and administration site conditions				
Pain	55	9	44	8
Asthenia/Fatigue	42	10	33	5
Fever	20	0	7	0
Vascular disorders				
Hypertension	31	15	6	5
Hemorrhage [b]	18	5	16	8
Gastrointestinal disorders				
Diarrhea	41	3	15	0
Nausea	17	<1	13	0
Vomiting	13	<1	7	<1
Mucositis	13	1	2	≤1
Respiratory, thoracic and mediastinal disorders				
Dysphonia	18	0	2	0
Infections and infestations				
Infection [b]	31	8	18	6
Metabolism and nutrition disorders				
Decreased appetite and food intake	31	3	15	2
Investigations				
Weight loss	13	2	4	0
Musculoskeletal and connective tissue disorders				
Muscle spasms	10	0	2	0

[a] Adverse reactions graded according to NCI CTCAE v4.0.
[b] Fatal outcomes observed.

Other clinically significant adverse reactions observed in less than 10% of STIVARGA-treated patients were: alopecia (7%), hypothyroidism (6.4%), pancreatitis (1.6%), exfoliative rash (1.3%), tremor (1.3%), erythema multiforme (0.8%), myocardial ischemia (0.8%), gastrointestinal fistula (0.3%), and myocardial infarction (0.3%).

Table 6 provides laboratory abnormalities observed in RESORCE.

Table 6: Laboratory test abnormalities reported in RESORCE

Laboratory Parameter	STIVARGA (N=374 [a])			Placebo (N=193 [a])		
	Grade [b]			Grade [b]		
	All %	3 %	4 %	All %	3 %	4 %
Blood and lymphatic system disorders						
Thrombocytopenia	63	5	<1	50	0	0
Neutropenia	14	3	0	15	<1	<1
Lymphopenia	68	16	2	59	11	<1
Metabolism and nutrition disorders						
Hypocalcemia	23	<1	0	10	0	0
Hypokalemia	31	4	<1	9	2	0
Hypophosphatemia	70	32	2	31	7	0
Hepatobiliary disorders						
Hyperbilirubinemia	78	13	3	55	11	5
Increased AST	93	16	2	84	17	3
Increased ALT	70	6	<1	59	5	0
Renal and urinary disorders						
Proteinuria [c]	51	17	- [d]	37	3	- [d]
Investigations						
Increased INR	44	<1	- [d]	35	2	- [d]
Increased Lipase	41	11	3	27	8	1
Increased Amylase	23	3	<1	19	2	<1

[a] Percent based on number of patients with post-baseline samples which may be less than 374 (regorafenib) or 193 (placebo).
[b] NCI CTCAE v4.0.
[c] Based on dipstick data.
[d] No Grade 4 denoted in NCI CTCAE v4.0.

6.2 Postmarketing Experience

The following adverse reaction has been identified during postapproval use of STIVARGA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:

- hypersensitivity reaction

7 DRUG INTERACTIONS

7.1 Effect of Strong CYP3A4 Inducers on Regorafenib

Co-administration of a strong CYP3A4 inducer with STIVARGA decreased the plasma concentrations of regorafenib, increased the plasma concentrations of the active metabolite M-5, and resulted in no change in the plasma concentrations of the active metabolite M-2 *[see Clinical Pharmacology (12.3)]*, and may lead to decreased efficacy. Avoid concomitant use of STIVARGA with strong CYP3A4 inducers (e.g. rifampin, phenytoin, carbamazepine, phenobarbital, and St. John's Wort).

7.2 Effect of Strong CYP3A4 Inhibitors on Regorafenib

Co-administration of a strong CYP3A4 inhibitor with STIVARGA increased the plasma concentrations of regorafenib and decreased the plasma concentrations of the active metabolites M-2 and M-5 *[see Clinical Pharmacology (12.3)]*, and may lead to increased toxicity. Avoid concomitant use of STIVARGA with strong CYP3A4 inhibitors (e.g. clarithromycin, grapefruit juice, itraconazole, ketoconazole, nefazodone, posaconazole, telithromycin, and voriconazole).

7.3 Effect of Regorafenib on Breast Cancer Resistance Protein (BCRP) Substrates

Co-administration of STIVARGA with a BCRP substrate increased the plasma concentrations of the BCRP substrate *[see Clinical Pharmacology (12.3)]*. Monitor patients closely for signs and symptoms of exposure related toxicity to the BCRP substrate (e.g. methotrexate, fluvastatin, atorvastatin). Consult the concomitant BCRP substrate product information when considering administration of such products together with STIVARGA.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on animal studies and its mechanism of action, STIVARGA can cause fetal harm when administered to a pregnant woman. There are no available data on STIVARGA use in pregnant women. Administration of regorafenib was embryolethal and teratogenic in rats and rabbits at exposures lower than human exposures at the recommended dose, with increased incidences of cardiovascular, genitourinary, and skeletal malformations *[see Data]*. Advise pregnant women of the potential hazard to a fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 % and 15 to 20%, respectively.

Data

Animal Data

In embryo-fetal development studies, a total loss of pregnancy (100% resorption of litter) was observed in rats at doses as low as 1 mg/kg (approximately 6% of the recommended human dose, based on body surface area) and in rabbits at doses as low as 1.6 mg/kg (approximately 25% of the human exposure at the clinically recommended dose measured by AUC).

In a single dose distribution study in pregnant rats, there was increased penetration of regorafenib across the blood-brain barrier in fetuses compared to dams. Daily administration of regorafenib to pregnant rats during organogenesis resulted in fetal findings of delayed ossification at doses ≥ 0.8 mg/kg (approximately 5% of the recommended human dose based on body surface area) and dose-dependent increases in skeletal malformations including cleft palate and enlarged fontanelle at doses ≥ 1 mg/kg (approximately 10% of the

clinical exposure based on AUC). At doses ≥ 1.6 mg/kg (approximately 11% of the recommended human dose based on body surface area), there were dose-dependent increases in the incidence of cardiovascular malformations, external abnormalities, diaphragmatic hernia, and dilation of the renal pelvis.

In pregnant rabbits administered regorafenib daily during organogenesis, there were findings of ventricular septal defects evident at the lowest tested dose of 0.4 mg/kg (approximately 7% of the AUC in patients at the recommended dose). At doses of ≥ 0.8 mg/kg (approximately 15% of the human exposure at the recommended human dose based on AUC), administration of regorafenib resulted in dose-dependent increases in the incidence of additional cardiovascular malformations and skeletal anomalies, as well as significant adverse effects on the urinary system including missing kidney/ureter; small, deformed and malpositioned kidney; and hydronephrosis. The proportion of viable fetuses that were male decreased with increasing dose in two rabbit embryo-fetal toxicity studies.

8.2 Lactation

Risk Summary

There are no data on the presence of regorafenib or its metabolites in human milk, the effects of regorafenib on the breastfed infant, or on milk production. In rats, regorafenib and its metabolites are excreted in milk. Because of the potential for serious adverse reactions in breastfed infants from STIVARGA, do not breastfeed during treatment with STIVARGA and for 2 weeks after the final dose.

8.3 Females and Males of Reproductive Potential

Contraception

Females

Use effective contraception during treatment and for 2 months after completion of therapy.

Males

Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 2 months following the final dose of STIVARGA *[see Nonclinical Toxicology (13.1)]*.

Infertility

There are no data on the effect of STIVARGA on human fertility. Results from animal studies indicate that regorafenib can impair male and female fertility *[see Nonclinical Toxicology (13.1)]*.

8.4 Pediatric Use

The safety and efficacy of STIVARGA in pediatric patients less than 18 years of age have not been established.

Animal Data

In 28-day repeat-dose studies in rats there were dose-dependent findings of dentin alteration and angiectasis. These findings occurred at regorafenib doses as low as 4 mg/kg (approximately 25% of the AUC in humans at the recommended dose). In 13-week repeat-dose studies in dogs there were similar findings of dentin alteration at doses as low as 20 mg/kg (approximately 43% of the AUC in humans at the recommended dose). Administration of regorafenib in these animals also led to persistent growth and thickening of the femoral epiphyseal growth plate.

8.5 Geriatric Use

Of the 1142 STIVARGA-treated patients enrolled in randomized, placebo-controlled trials, 40% were 65 years of age and over, while 10% were 75 and over. No overall differences in efficacy were observed between these patients and younger patients. There was an increased incidence of Grade 3 hypertension (18% versus 9%) in the placebo-controlled trials among STIVARGA-treated patients 65 years of age and older as compared to younger patients. In addition, one Grade 4 hypertension event has been reported in the 65 years and older age group and none in the younger age group.

8.6 Hepatic Impairment

No dose adjustment is recommended in patients with mild (total bilirubin ≤ULN and AST >ULN, or total bilirubin >ULN to ≤1.5 times ULN) or moderate (total bilirubin >1.5 to ≤3 times ULN and any AST) hepatic impairment, *[see Clinical Pharmacology (12.3)]*. Closely monitor patients with hepatic impairment for adverse reactions *[see Warnings and Precautions (5.1)]*.

STIVARGA is not recommended for use in patients with severe hepatic impairment (total bilirubin >3x ULN) as STIVARGA has not been studied in this population.

8.7 Renal Impairment

No dose adjustment is recommended for patients with renal impairment. The pharmacokinetics of regorafenib have not been studied in patients who are on dialysis and there is no recommended dose for this patient population *[see Clinical Pharmacology (12.3)]*.

8.8 Race

Based on pooled data from three placebo-controlled trials (CORRECT, GRID and CONCUR), a higher incidence of HFSR and liver function test abnormalities occurred in Asian patients treated with STIVARGA as compared with Whites *[see Warnings and Precautions (5.1, 5.5)]*. No starting dose adjustment is necessary based on race.

10 OVERDOSAGE

The highest dose of STIVARGA studied clinically is 220 mg per day. The most frequently observed adverse drug reactions at this dose were dermatological events, dysphonia, diarrhea, mucosal inflammation, dry mouth, decreased appetite, hypertension, and fatigue. There is no known antidote for STIVARGA overdose. In the event of suspected overdose, interrupt STIVARGA, institute supportive care, and observe until clinical stabilization.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies examining the carcinogenic potential of regorafenib have not been conducted. Regorafenib itself did not demonstrate genotoxicity in in vitro or in vivo assays; however, a major human active metabolite of regorafenib, (M-2), was positive for clastogenicity, causing chromosome aberration in Chinese hamster V79 cells.

Dedicated studies to examine the effects of regorafenib on fertility have not been conducted; however, there were histological findings of tubular atrophy and degeneration in the testes, atrophy in the seminal vesicle, and cellular debris and oligospermia in the epididymides in male rats at doses similar to those in human at the clinical recommended dose based on AUC. In female rats, there were increased findings of necrotic corpora lutea in the ovaries at the same exposures. There were similar findings in dogs of both sexes in repeat dose studies at exposures approximately 83% of the human exposure at the recommended human dose based on AUC. These findings suggest that regorafenib may adversely affect fertility in humans.

13.2 Animal Toxicology and/or Pharmacology

In a chronic 26-week repeat dose study in rats there was a dose-dependent increase in the finding of thickening of the atrioventricular valve. At a dose that resulted in an exposure of approximately 12% of the human exposure at the recommended dose, this finding was present in half of the examined animals.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Hepatotoxicity

Advise patients that they will need to undergo monitoring for liver damage and to report immediately any signs or symptoms of severe liver damage to their healthcare provider *[see Warnings and Precautions (5.1), Use in Specific Populations (8.6)]*.

Infections

Advise patients to contact their healthcare provider if they experience signs and symptoms of infection *[see Warnings and Precautions (5.2)]*.

Hemorrhage

Advise patients to contact their healthcare provider for unusual bleeding, bruising, or symptoms of bleeding, such as lightheadedness *[see Warnings and Precautions (5.3)]*.

Gastrointestinal Perforation or Fistula

Advise patients to contact a healthcare provider immediately if they experience severe pains in their abdomen, persistent swelling of the abdomen, high fever, chills, nausea, vomiting, or dehydration *[see Warnings and Precautions (5.4)]*.

Dermatologic Toxicity

Advise patients to contact their healthcare provider if they experience skin changes including HFSR, rash, pain, blisters, bleeding, or swelling *[see Warnings and Precautions (5.5)]*.

Hypertension

Advise patients they will need to undergo blood pressure monitoring and to contact their healthcare provider if blood pressure is elevated or if symptoms from hypertension occur including severe headache, lightheadedness, or neurologic symptoms *[see Warnings and Precautions (5.6)]*.

Cardiac Ischemia and Infarction

Advise patients to seek immediate emergency help if they experience chest pain, shortness of breath, feel dizzy, or feel like passing out *[see Warnings and Precautions (5.7)]*.

Reversible Posterior leukoencephalopathy syndrome

Advise patients to contact their healthcare provider if they experience signs and symptoms of RPLS *[see Warnings and Precautions (5.8)]*.

Wound Healing Complications

Advise patients to contact their healthcare provider if they plan to undergo a surgical procedure or had recent surgery *[see Warnings and Precautions (5.9)]*.

Embryo-Fetal Toxicity

Advise patients that regorafenib can cause fetal harm. Advise a pregnant woman of the potential risk to a fetus *[see Warnings and Precautions (5.10), Use in Specific Populations (8.1, 8.3)]*.

Females and Males of Reproductive Potential

- Advise women of reproductive potential of the need for effective contraception during STIVARGA treatment and for 2 months after completion of treatment. Instruct women of reproductive potential to immediately contact her healthcare provider if pregnancy is suspected or confirmed during or within 2 months of completing treatment with STIVARGA *[see Warnings and Precautions (5.10) and Use in Specific Populations (8.1, 8.3)]*.
- Advise men of reproductive potential of the need for effective contraception during STIVARGA treatment and for 2 months after completion of treatment *[see Use in Specific Populations (8.3)]*.

Lactation

Advise nursing mothers that it is not known whether regorafenib is present in breast milk and discuss whether to discontinue nursing or to discontinue regorafenib *[see Use in Specific Populations (8.2)]*.

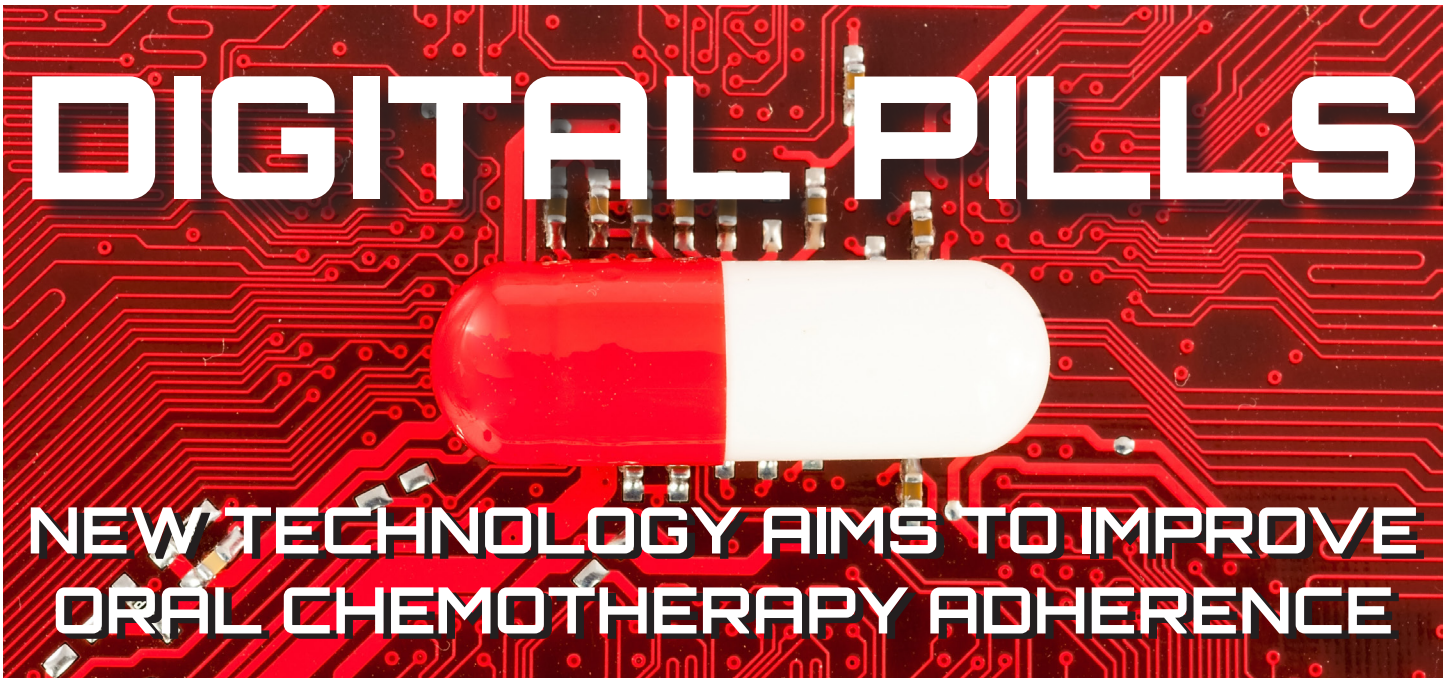
Administration

- Advise patients to swallow the STIVARGA tablet whole with water at the same time each day following a low-fat meal. Inform patients that the low-fat meal should contain less than 600 calories and less than 30% fat *[see Dosage and Administration (2.1)]*.
- Advise patients to store medicine in the original container. Do not place medication in daily or weekly pill boxes. Discard any remaining tablets 7 weeks after opening the bottle. Tightly close bottle after each opening and keep the desiccant in the bottle *[see How Supplied (16)]*.

Dosing Instructions

Advise patients to take STIVARGA after a low fat meal. Advise patients to take any missed dose on the same day, as soon as they remember, and that they must not take two doses on the same day to make up for a dose missed on the previous day *[see Dose and Administration (2.1)]*.

Manufactured for:
Bayer HealthCare Pharmaceuticals Inc.
Whippany, NJ 07981 USA
 6708306BS



DIGITAL PILLS

NEW TECHNOLOGY AIMS TO IMPROVE ORAL CHEMOTHERAPY ADHERENCE

By Kirollos Hanna, PharmD, BCPS, BCOP

Oral chemotherapies have become a part of standard care treatments in the management of various malignancies in cancer care.

Their use continues to expand and offers novel mechanisms of action in treating cancer as a "chronic" condition within the home.

Optimizing adherence and compliance for oral therapies remains a barrier. Some patients have complex regimens, some experience side effects and others simply forget to take their medication.

Kirollos Hanna

Interventions such as digital bottle caps, electronic medical record reminders, phone calls and calendars have been utilized to assess adherence and compliance, but have proved insufficient at times.

Now a new technology, digital pills, promises to help clinicians assess adherence and compliance in real time.

Digital pills come in various forms. They are activated by the digestive process, which causes them to transmit to external receivers worn by patients. The receivers then relay that information to software loaded onto the patients' smartphones or tablets.

Two notable companies of such technologies include etectRx and Proteus Digital Health.

Both companies utilize capsules as the primary delivery method for the technology in which the parent drug would be placed in and ingested.

The etectRx ID-Capsule is a standard hard gelatin capsule with an embedded ingestible wireless sensor – the ID-Tag. Each time an ID-Capsule is swallowed, the ID-Tag uses etectRx's proprietary communications technology to transmit a very low power digital message after ingestion.

The Reader is a wearable device that detects messages transmitted from ingested ID-Tags and forwards them using Bluetooth technology to the ID-Cap App on the patient's smartphone. The ID-Cap App relays the messages received by the Reader to a cloud-based secure server, allowing patients and care teams to view drug adherence and event history.

In contrast, Proteus Digital Health capsules are comprised of elements found in a typical diet. Once ingested, a Bluetooth-enabled patch is worn to detect the ingested capsule. This patch communicates with a smartphone or tablet, which then links to an online portal.

Upon dissolution in the gastrointestinal tract, these products are eliminated naturally.

Real-time alerts and access to an online portal enable clinicians to assess how many pills a patient took, how far apart doses were, and whether doses were missed. In some cases, these platforms offer additional information, such as resting heart rate.

In 2012, Proteus became the first company to receive FDA clearance for marketing an ingestible sensor.

In 2017, the company received FDA approval to combine this sensor with medication in a single pill: the Abilify MyCite system.[1]

Proteus is the first to trial "digital therapy" in cancer care.[2]

The new digital technologies offer unique modalities that can help

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DIGITAL PILLS

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clinicians and teams assess patient adherence and compliance. Yet they are not without adaptability considerations, including safe handling of oral chemotherapy, device convenience, ease of use, cost and marketability.

Oral chemotherapies require handling precautions in order to ensure safe use and to minimize unnecessary environmental exposure. The available digital capsules require manipulation of drug products prior to dispensing to patients.

As a result, healthcare personnel must handle oral chemotherapies and encapsulate each pill, which could potentially lead to unnecessary exposure. Safe handling precautions must be in place to minimize such exposure.

Except with systems similar to Abilify MyCite, this will likely be a major hurdle to full adaptation of these technologies.

Device convenience and ease of use may also become an issue for patients unwilling to wear a Reader for the ID-Tags, or a patch.

Many patients with cancer are often already burdened with their diagnosis and outcomes, cost, treatment, follow up and the numerous other aspects of cancer care.

Others may not be interested in this "big brother" model of assessments and having to deal with a patch or reader.

Also, some patients may not be savvy enough to handle the technology. Such patients, however, could still use some type of Bluetooth-enabled device to transmit information to an online portal.

Cost and marketability of these technologies is also a concern. How much these devices will cost and who will be responsible for them still remains unknown.

Whether or not digital pills will be available as a medical device versus another formulation of a drug product is still not clear. As a result, how these technologies will be incorporated into electronic medical records, billed and prescribed will add other challenges.

One final consideration: should these technologies prove a patient non-adherent or non-compliant despite interventions, could payers deny coverage or access to therapy if given access to the data?

Adherence and compliance of oral chemotherapy is important to ensure safe and effective use of drugs. Digital pills offer a possible solution. Yet several barriers exist with the current available strategies that will need to be addressed for better adaptability across cancer care centers.

▲ **Kirollos Hanna**, PharmD, BCPS, BCOP, is an Assistant Professor of Pharmacy at the Mayo Clinic College of Medicine and a Hematology/Oncology Clinical Pharmacist at the University of Minnesota Medical Center.

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MIAMI CANCER INSTITUTE

MISSION STATEMENT: Miami Cancer Institute provides comprehensive care to patients with cancer and their families in a multi-disciplinary setting with the most innovative, evidence-based approaches available. We focus on compassionate care, delivered in a timely manner, with ready access to highly skilled and professional teams of caregivers.

VISION: We strive to be the preferred treatment destination for patients with cancer and their families – locally, regionally and internationally. Our team works together to accelerate progress toward our ultimate goal of finding a cure. Miami Cancer Institute brings together world-class cancer experts and an unmatched dedication to multidisciplinary patient care, cutting-edge technology and innovative cancer treatments. Enhanced by an alliance with Memorial Sloan Kettering – a leading academic cancer center – our 140,000-square-foot research facility provides patients access to clinical trials and ground-breaking treatments that could lead to positive outcomes.

ADDRESS: 8900 N. Kendall Drive, Miami, Florida.

PRACTICE DETAILS: The Miami Cancer Institute has about 1,300 employees, including 82 physicians and 106 advance practice providers.

QUALIFICATIONS/CREDENTIALS: The institute has a unique partnership with Memorial Sloan Kettering Cancer Center. Additionally we are certified by QOPI and the Commission on Cancer.

PHARMACY SERVICES: The institute has an oncology sub-specialized and decentralized pharmacy practice model, bringing pharmacy professionals to infusion suites and clinics, allowing for more readily available pharmacy services and close interaction with patients and the multidisciplinary care team. Primary pharmacy service lines include standard of care infusion, investigational drug services infusion, inpatient/outpatient auto- and allogeneic bone marrow transplant, and oral oncolytic monitoring services. Pharmacy services are expanding rapidly to meet the demands of a growing oncology program.

STAFF: The pharmacy team is composed of pharmacy technicians, pharmacy auditors, pharmacy residents, oncology-specialized informatics pharmacists, clinical pharmacists, clinical pharmacy specialists, pharmacy coordinators, supervisors, managers, a pharmacy director and an assistant vice president of oncology pharmacy.

DISPENSING TYPE: The Miami Cancer Institute houses its own specialty pharmacy, which provides services throughout the health system. This pharmacy has specialized dispensing and monitoring clinical teams to provide oncology-specific services.

SERVICES PROVIDED: Radiation therapy, interventional oncology, genetic counseling and testing, pediatric cancer care, surgery, diagnostic testing, clinical trials and research, preventative screenings, proton therapy and chemotherapy outpatient infusion services.

WHY DID YOU JOIN NCODA? NCODA has a patient advocacy focused mission which aligns with our goals and mission. Additionally, NCODA provides the opportunity to understand how health systems and different dispensary settings can collaborate and partner to advance the patient experience with oral specialty treatments.

HOW DID YOU BECOME A MEMBER? By connecting with the NCODA leadership team and learning the different ways the organization can position practices to better meet evolving patient needs.

HOW DID YOU HEAR ABOUT US? Through a networking event.

HOW CAN NCODA HELP YOU? Having access to Quality Standards as well as Oral Chemotherapy Education sheets for patients will greatly improve the care and the information that we provide.

WHAT ARE SOME OF THE ONCOLOGY CHALLENGES ARE YOU FACING? Limited access to oral oncology agents presents challenges, specially in the health-system setting. With the emergence of an increasing number of oral oncology treatments available, we see benefits in terms of quality of life and convenience; however, the high complexity associated with these regiments and the home care setting continues to elevate patient monitoring challenges and safety concerns. As an ambulatory medical community, we have the need to developed more effective strategies to help patients drive the most benefit from these treatments while keeping them safe.

BE OUR NEXT PRACTICE IN FOCUS

NCODA is committed to creating a collaborative community environment, providing a platform for practice members to share common experiences and help one another succeed. Practice in Focus connects practices to one another as we all strive to provide better care to patients.

The Practice in Focus application process is simple and takes approximately 20 minutes to complete. Once an application is submitted, NCODA will help develop an online profile for the respective practice.

Practice in Focus participants have the opportunity to talk about their practice each month during the NCODA National Monthly Webinar, an ideal way to highlight the work being done within their facility.

In order to be considered for selection:

- An application is completed and submitted by an NCODA member
- Applications are considered when one person from each facet of the practice/organization's medically integrated team (i.e. doctor, nurse, pharmacist, pharmacy technician, financial counselor, etc.) is an NCODA member
- One or more members of your medically integrated team will present during the National Monthly Webinar as the featured practice

For an application, visit **www.ncoda.org/practice-in-focus.**

MANAGING AN ORAL ONCOLOYTIC IS ALSO A CHALLENGE FOR THE PATIENT

Managing a cancer patient's oral chemotherapy treatment can be an ongoing challenge for the Medically Integrated Pharmacy team.

But then again, it's no walk in the park for the patient, either.

I'm about six years into what will be a lifelong battle with multiple myeloma, which has so far included a year of infusion therapy, two stem cell transplants and now, during my remission, three and half years of an oral oncolytic maintenance regimen.

Bill Wimbiscus

From what I've read about oral oncolytics, these regimens often can be a tricky business involving different dosages on different days, along with a host of safety issues, side effects and adherence concerns that require constant monitoring by healthcare specialists.

Fortunately for me, my 10 mg Revlimid regimen is fairly simple: 14 days on, 7 days off.

Given its potential for causing possible birth defects, safety concerns are a big deal, requiring me to take a monthly phone survey with Celgene, the biopharmaceutical company that manufactures the drug. The monthly survey goes something like this:

▲ **Have you missed any doses?** Press 1 for Yes, Press 2 for No.

I've rarely missed a dose. I take the pill around the same time every evening, shortly after I take my other nightly pills. I also try to keep track of the number of pills left in the bottle each day as a way to ensure adherence. So that's a 2.

▲ **Have you shared your Revlimid with anyone?** Press 1 for Yes, Press 2 for No.

I always think, "You've got to be kidding" on this one. Since it now costs around $800 a pill, I don't plan on *ever* sharing my Revlimid stash with anyone. Again, a 2.

▲ **Have you had unprotected sex with a woman of child-bearing age while on Revlimid?** Press 1 for Yes, Press 2 for No.

Wow. Kind of a personal question, right? Fortunately, given my age and looks, this one's pretty easy to answer: 2.

So far, I've taken around 40 surveys, and I'm still batting 1,000. And my answers are always the same: 2-2-2.

Really, the only things that complicate my regimen are a couple of side effects – fatigue and gastric distress – and my abysmal blood cell counts.

Since Revlimid basically works by suppressing the immune system, my monthly white and red blood cell counts are always at the low end of the normal range, and sometimes even below it.

Living with a suppressed immune system can be a real challenge. During my first couple years of maintenance therapy, respiratory infections were a constant problem.

Taking antihistamines and mucus thinners have helped lessen their occurrence, as have early flu vaccinations.

Still, it's likely inevitable that I'm going to be popping antibiotics or even prednisone at some point.

Yet, as I found out earlier this year, it's not just respiratory infections that I have to worry about.

As I mentioned in my last column, I was diagnosed with a bad sepsis infection in March. I was hospitalized for nine days, during which time my five-year-old infusion port was removed and a two-week course of cefazolin was begun.

After my release, I went to see a specialist about the ongoing neck pain that had driven me to the hospital in the first place. The specialist took some X-rays, made some measurements and eventually diagnosed scoliosis and spondylosis as the cause of the pain.

It was around this time I first found the "bump." One day, while to trying massage the kinks out of my aching neck, I noticed a mass about the size of golf ball on my upper right chest.

I mentioned it to the specialist, who said it was likely a muscle spasm caused by the spondylosis, and that it would probably go away by itself.

Later, during my monthly myeloma checkup, I almost forgot to mention my "spondylosis bump" to my oncologist.

"Bump?" he said, and suddenly the conversation got real serious real fast.

After a couple of scans, he said it was most likely one of two things: either a return of my myeloma, or a plasmacytoma, which is a localized tumor associated with myeloma. He recommended I meet with my myeloma specialist to determine a final diagnosis.

Three weeks later, after numerous MRIs, PET scans, CAT scans and a biopsy, my myeloma specialist gave me a final diagnosis. It basically was this: "I don't know what it is, but it's definitely not multiple myeloma or a plasmacytoma. I recommend you go see an infectious disease specialist."

So I went to see the infectious disease specialist, who promptly stuck a PICC line in my arm and put me back on cefazolin for another six weeks. You know, just in case.

Over the course of those three months, I had to stop and restart my Revlimid treatment several times.

But here, finally, is the point: since my prescription is through an NCODA-affiliated Medically Integrated Pharmacy, stopping and restarting my Revlimid was simple, seamless and hassle-free. And considering I could be taking these pills the rest of my life, that's a pretty big deal to me.

▲ *Oncolytics Today* Editor **Bill Wimbiscus** is a journalist and cancer survivor who lives near Chicago.

This Is What the Future of Metastatic Breast Cancer Will Look Like

1 Over the past year, what do you believe are the most notable advancements in breast cancer care?

Certainly, one of the most notable things is the sheer pace of innovation in the oncology space. With new drug approvals and more data about sequencing and combination treatments, we are seeing practice-changing innovations that provide an improved survival benefit. Along with significant survival benefits comes the need to continue developing treatments that are also safer, less toxic, and that have less side effects. These are the issues that can really impact quality of life for patients and, in some cases, make it challenging for them to stay on therapy over time. We believe that some of the most valuable advancements are treatments that allow patients to live life on their own terms. Specifically, women with metastatic breast cancer need more options that improve survival without sacrificing their ability to participate in activities of daily life.

2 What new practices can breast cancer doctors and nurses implement right now to help improve patient care?

As we collaborate with the oncology community, we hear from patients, caregivers, and health care professionals that it is very important for women with metastatic breast cancer to feel 'more like people and less like patients.' This can be accomplished in a variety of ways, such as using communication tools to understand patient goals, providing questionnaires to measure distress, and considering new treatments that balance efficacy and side effect profiles with patient lifestyles. This is an important concept because we all want to make a meaningful difference in the lives of patients and support them in every aspect of their lives. We are all for taking steps to help women with metastatic breast cancer feel more like themselves.

3 How has new technology changed the ability to care for cancer patients?

IV chemotherapy, which has been foundational to metastatic breast cancer treatment, comes with significant limitations and adverse reactions. Patients must make time to travel to IV infusion clinics and stay for hours at a time. Also, receiving chemotherapy through an IV infusion can lead to side effects that impact treatment and quality of life. In the past, the ability to take some chemotherapy by mouth has been limited because the chemotherapy has not been well absorbed in the gastrointestinal tract. New drug technology such as our Orascovery platform, may allow patients to receive chemotherapy by mouth, which can help improve the treatment experience. This may help address some of these drawbacks and improve the treatment experience. With breast cancer being the most common cancer among women in the U.S. and around the world, our hope is that new technologies will improve the quality of life for patients.

4 How do you envision cancer care will change and adapt in the next ten years?

We feel strongly that cancer care is going to keep improving over time. First, treatments are evolving to provide longer survival with improved quality of life… and many can be received at home, on the patient's terms. Second, technology in the health care industry is advancing cancer care by connecting health care professionals who are part of the same "care team." It allows each person to know what others are doing, which helps paint a more complete picture of every patient they see. When information is shared by health care professionals in the same network, it leads to comprehensive care and potentially better results. All of this adds up to better care of those who have metastatic breast cancer…so they can feel more like people and less like patients.

Timothy Cook is senior vice president of Global Oncology at Athenex Oncology, a US-based, global biopharmaceutical company dedicated to the discovery, development, and commercialization of novel therapies for the treatment of cancer. A former Bristol-Myers Squibb and Lilly alum, Cook has dedicated his career to serving patients, health care professionals, and caregivers by bringing novel oncologic therapies to market in the US, Europe, and Japan.

Above, Thomas Gallo, MS, MDA, of the Virginia Cancer Institute, discusses vertical integration with pharmaceutical representatives during the 2019 NCODA Oncology Institute. Below, left, more than 180 industry representatives turned out for the first-of-its-kind institute.

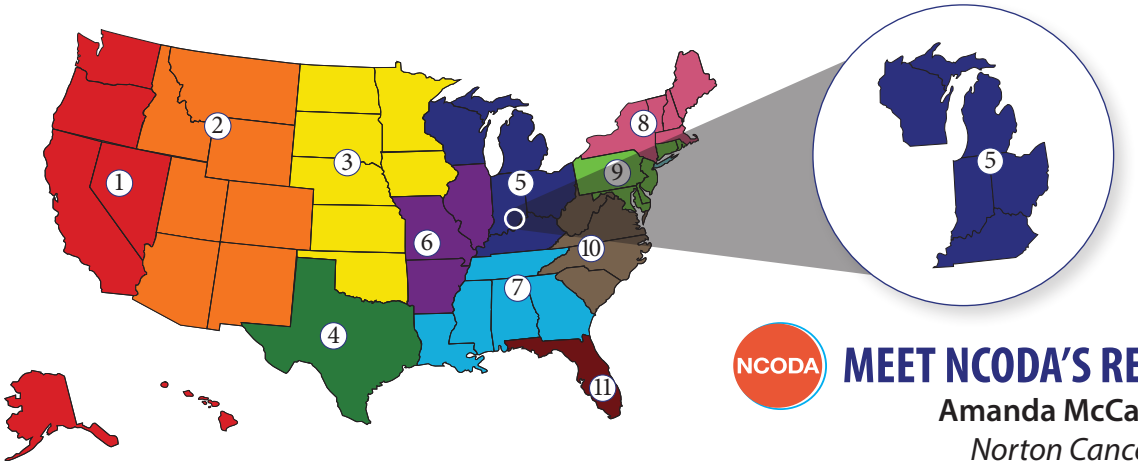
A GROUNDBREAKING EVENT

More than 180 representatives of the pharmaceutical industry attended the first-of-its-kind **NCODA Oncology Institute** on Aug. 21 in Chicago. The institute, "Understanding the Challenges Oncology Patients and Practices Face Today," was hosted by 20 practice leaders and NCODA Executive Council members. Sessions included establishment of meaningful relationships with practices, PBMs and their impact on community oncology, vertical integration, updates on USP 797 and 800, implementation of biosimilars and upcoming legislation.

PHOTOS BY BILL WIMBISCUS

Institute panelists (from left) Lisa Raff, PharmD, Northwest Oncology & Hematology, Kashyap Patel, MD, Carolina Blood and Cancer Care, and Ali McBride, PharmD, University of Arizona Cancer Center, discuss "Implementing Biosimilars at Your Practice."

REGION 5 LEADER AMANDA McCAULEY VALUES INTERACTION WITH HER PEERS



NCODA

MEET NCODA'S REGION 5 LEADER

Amanda McCauley, BSN, RN, OCN

Norton Cancer Institute, Kentucky

By Rebecca Corvese, PharmD

Amanda McCauley, BSN, RN, OCN, is NCODA's Regional Leader for Region 5 – Indiana, Kentucky, Michigan, Ohio and Wisconsin.

McCauley was recruited to NCODA by Mary Anderson, who was able to convey to her all that NCODA had to offer.

Soon after meeting Anderson, McCauley attended her first NCODA meeting, the 2018 Spring Forum. Similar to her years spent at the University of Louisville, she was eager to get involved.

Her favorite part of NCODA membership is interacting with members across the country. She is grateful to be part of a community that has the same passion for oncology that she developed during her nursing career.

McCauley first chose to pursue nursing in high school when her grandmother fell ill. She was inspired by the care and compassion she saw the nurses provide for her grandmother.

After completing nursing school, she started working in an oncology transitions care unit, where she fell in love with her career. Today, McCauley can be found in her hometown of Louisville, Kentucky, as a full-time nurse at the Norton Cancer Institute.

McCauley considers her mother an amazing role model – she worked full-time, raised two children and is now bravely fighting stage IV melanoma.

Asked what motivates her, McCauley said that being able to go out and make a difference in a cancer patient's life is what gets her through a long day.

McCauley says that making a difference in a cancer patient's life is what gets her through a long day.

And to unwind after those long days? She likes to take a hot bath or play with her cat, Lady. She also enjoys going to visit her two young nieces.

Currently, McCauley is vice president of her local Oncology Nursing Society chapter. She considers this position, as well as being recognized as Norton's Oncology Nurse of the Year in 2018, her biggest professional accomplishments.

If given the opportunity to send a message to her younger self, McCauley would say, "Stick with it! Don't be afraid to take chances. Get involved and learn new things."

She describes herself as funny, optimistic and a bookworm. Her Kindle is full of romance and science fiction novels. Her personal motto: "Don't sweat the small stuff!"

McCauley is looking forward to the NCODA Fall Summit 2019 in Orlando, Florida, where she plans to continue creating and maintaining meaningful relationships with professionals from across the medically integrated pharmacy community.

▲ **Rebecca Corvese**, PharmD, is the Oncology Association Management Fellow at NCODA.

CALLING ALL ONCOLOGY CLINICAL AND INDUSTRY PROFESSIONALS

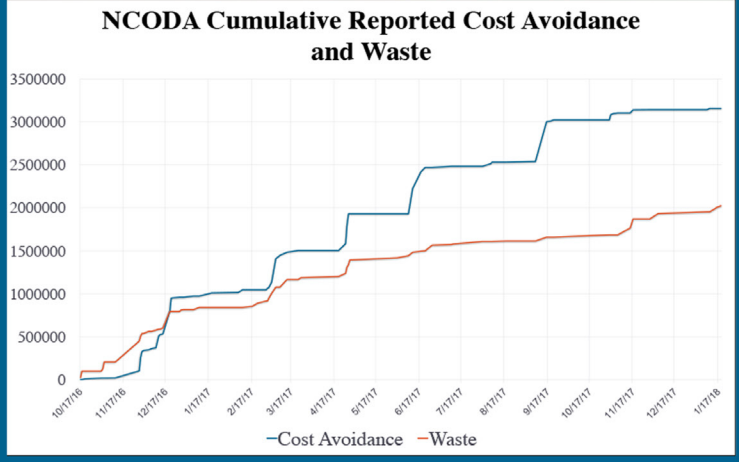
NCODA

Showcase Your Achievements to the Experts in Oncology

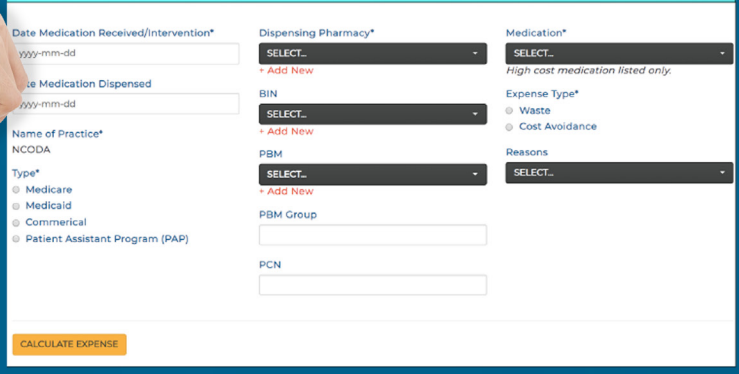
Cost avoidance through the medically integrated dispensary for oral chemotherapy: Utilizing the NCODA Cost Avoidance and Waste Tracker tools

This is a cost analysis of medication costs from voluntary data entries provided by NCODA member practices across the U.S. for 16 months from 2016 to 2018.

Results



Online Cost Avoidance and Waste Tracker



Do you have a research poster that you would like to share at one of NCODA's upcoming fall or spring national meetings?

Contact Josh Nubla for more information | joshua.nubla@ncoda.org

NCODA'S ADVANCED PHARMACY PRACTICE EXPERIENCE NOTHING SHORT OF AMAZING

NCODA's APPE offered me the opportunity to have an unmatched experience that will be instrumental in helping me achieve my career goals.

My last year of pharmacy school ushered in a wave of change and stark contrast to the structured curriculum to which I have been accustomed.

Gone are the days of passively absorbing presentations and lectures, imagining how one day the knowledge will translate to practice.

After facing a slate of rotations in varying settings, each bringing a unique set of challenges and insights, I am excited to begin directly impacting patient care.

Benjamin Bratek

As my time here at NCODA comes to an end, I can reflect back on what this experience has meant for me, not only as a student, but also for my professional development.

NCODA is unique in its range of offerings to **Advanced Pharmacy Practice Experience (APPE)** students, with some noteworthy experiences including: authoring **Positive Quality Interventions** documents utilized by thousands of healthcare professionals, editing **Oral Chemotherapy Education** sheets to ensure patient education is current and evidence-based, and presenting on various topics during meetings and webinars.

There is something for everyone, with opportunities to work both individually and as part of a multidisciplinary team on engaging projects.

The scope of activities at NCODA are wider than those offered by most traditional hospital or community APPEs, and the ability to reach patients on a large scale is unparalleled.

NCODA offered me the opportunity to have an unmatched experience that will be instrumental in helping me achieve my career goals. This will be the highlight of my *curriculum vitae* when showcasing project- and team-based leadership experiences and the skills I have gained to prospective residency programs or employers.

There have been countless informal career-development discussions with my preceptors – Mike, Josh, Matt and Rebecca – that show how much the staff here truly care.

The environment here is conducive not only to acquiring valuable management skills, but also to helping achieve one's goals.

Other rotations are aimed at ensuring students get the minimum level of required experiences to ensure baseline competence, while NCODA aims for excellent experiences for its students. The difference really shows!

Beyond the direct benefits to professional and educational development, NCODA has been a cherished experience on a personal level.

As a registered nurse, I am a patient advocate above all else. NCODA has allowed me to carry on this trait throughout my pharmacy journey.

Ensuring healthcare providers and patients are armed with the most accurate and current information and tools to take on cancer has been one of the most rewarding experiences for me.

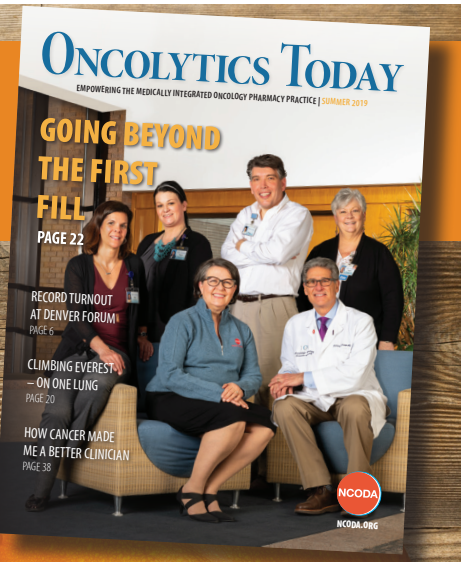
The collaborative, patient-centered approach NCODA takes to improve oncology care is contagious. An unavoidable consequence of my time at NCODA will be to take this mission with me throughout my career in pharmacy.

I would highly recommend this APPE elective rotation to any pharmacy student seeking a non-traditional experience that is challenging, enriching and will help prepare the student for leadership and management roles!

▲ **Benjamin Bratek**, RN, is a 2020 PharmD Candidate at Albany College of Pharmacy and Health Sciences in Albany, New York.

A HARVEST OF RESOURCES & INFORMATION

Join us in print and online for the latest news from NCODA

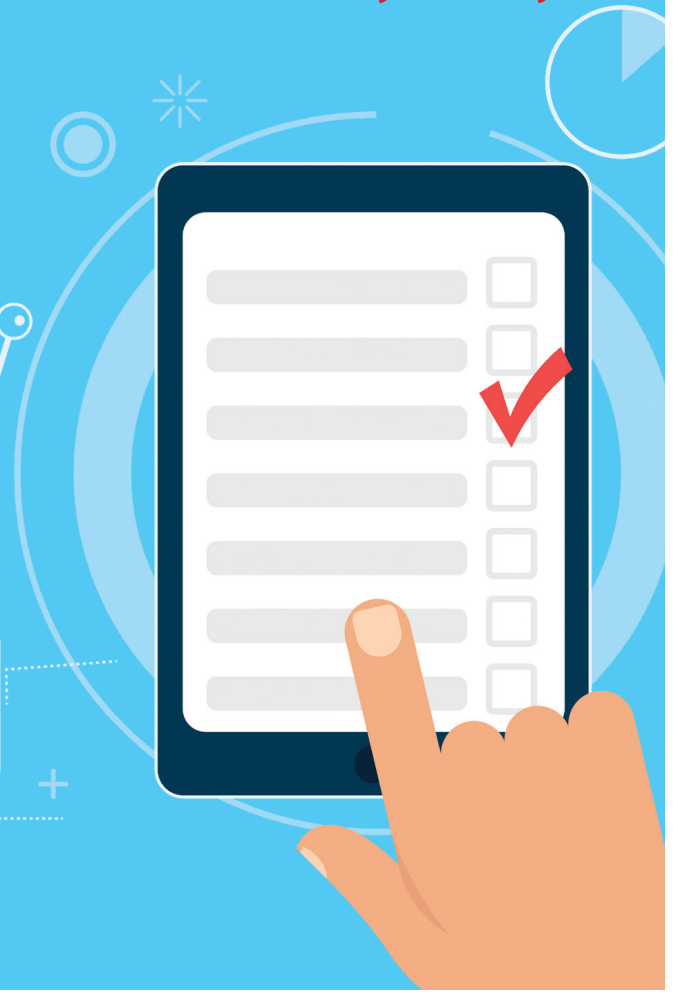


Start Utilizing the Patient Satisfaction Survey Today!

NCODA, in collaboration with **Syracuse University's Maxwell School**, has developed a Patient Satisfaction Survey.

This survey quantifies data that interests **patients**, **providers** and **payers**. Responses from this survey help us and our member organizations identify opportunities for improvement.

Over **1,200** surveys have been collected with a **95% overall satisfaction rate** from NCODA practices.



NCODA

Learn more at
www.ncoda.org/other

CHANGE YOUR LIFE FROM 'I SHOULD' TO 'I CAN'

Sean Swarner on the third day of his July 2018 CancerClimber expedition to the summit of Mount Kilimanjaro.

By Sean Swarner

What would you do with your life if you had a second chance? An opportunity to start over?

As far as I know, there's no such thing as a Mr. Peabody's Wayback Machine, but that doesn't mean your second chance can't start right now.

We all have habits in life, and those habits have been established through repetition (usually unconsciously), day after day, month after month, year after year. The decisions you made in your past, whether consciously or unconsciously, got you to where you are right now.

For so many years, I had to live day by day because my life with cancer was centered around the next doctor's check-up or chemo treatment. The possibilities for each day revolved around my energy (or lack thereof), and whether or not I felt like vomiting after chemotherapy.

It's incredibly hard to think about your future and fulfilling your potential when you're hugging a toilet.

My battle with cancer will always be part of my story, but it does not define me. Just like anything in your past doesn't define you or determine your future. You have the opportunity to decide what will. You get to decide what happens next, and it's exhilarating and intimidating at the same time.

After my cancers (at ages 13 and 16, with a prognosis of three months and then 14 days to live), I wanted to start living a life filled with meaning. I decided what I wanted to do with my second, or third chance at life, and I want to help you do the same.

What prevents you from living your best life right now? In one word: YOU. But there's so much more to unpack in that simple answer. During my training to become a Certified Professional Coach, I learned that our obstacles come from our own personal Gremlins, Associations, Interpretations and Limiting beliefs (GAILs).

What prevents you from living your best life right now? In one word: YOU.

The first step toward getting past these limitations is self-awareness. In my previous article, I mentioned that you speak to yourself more than anyone else. Start becoming aware of the words you use about and toward yourself.

For example, "should" is often a word we use in negative self-talk — "I should be further in my schooling, career, relationships, etc., than I am right now." Those thoughts stem from expectations that we or others have set for our lives and where we "should" be, based on cultural norms.

Instead, try to replace "I should" with "I can." This shifts the focus from the past — what you "should" have done — to the future and the actions that are within your control. If you postponed college due to something that happened in your life, for instance, you can shift the internal dialogue from "I should have finished college by now" to "I can go back to college this year to earn my degree."

There are two main types of motivators: intrinsic and extrinsic. Intrinsic motivation is when we do something

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'I CAN'

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because we find it inherently rewarding. For example, you go for a run outside because you enjoy it. You run simply because it makes you feel good.

Now, let's say you don't like running, but your office is doing a "Biggest Loser" competition, modeled after the TV show. Everyone at your office puts money in to participate and the person who loses the greatest percentage of their body weight wins the money. Now, you're running because of an extrinsic motivator — cash.

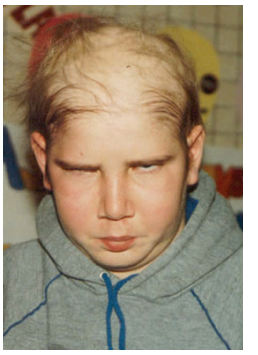
I want to help you find your intrinsic motivators. What values act as a guiding light in your life? For example, if you're inherently motivated to run, you might value your health. So, you make choices that align with that value, such as exercising and eating healthy.

Once we start straying away from and making decisions that don't align with our core values, we feel dissonance, we feel "off," we feel stressed.

Understanding what your values are is a tremendous help to getting yourself back on track to being happy and becoming the best version of yourself that you can be.

I have a Core Values Assessment to help you identify and understand your intrinsic motivators, which will help propel you toward your goals. Based on those findings, you can create a vision map, outlining the things you want to do with your life and how you'll get there.

Then, you will learn to make conscious decisions, based on your core values and what you want to achieve. Those conscious decisions will become your thoughts, your thoughts will become your actions, and your actions will become your habits.



Sean Swarner faced terminal cancer twice – at age 13 when he was given a prognosis of three months to live, and again at age 16, when he was told he had14 days to live.

Your life is a culmination of the habits you've established over time. If you want to change your life, change your habits.

So, I'll ask you again: What would you do with your life if you had a second chance?

Step into that reality today and start living the next 364 days to the fullest.

▲ **Sean Swarner** is a keynote speaker (NCODA 2019 Spring Forum), adventurer, Certified Professional Coach, author and world-record holder. To get a copy of Sean's Core Values Assessment, email him at sean@cancerclimber.org.

PROVIDED PHOTO BY LARIVIÈRE ET MASSICOTTE PHARMACIENNE

Larivière et Massicotte Pharmaciennes Inc. is an independent Canadian pharmacy, based in Montreal dedicated exclusively to specialty medications.

LARIVIÈRE ET MASSICOTTE PHARMACIENNES

NCODA strives to collaborate with international organizations with similar values towards benefiting patient care.

Larivière et Massicotte Pharmaciennes, Inc., in Montreal, Quebec, is one such organization.

In this issue of ***Oncolytics Today***, Mannar Dayoub, BPharm, Director of Pharmaceutical Care and Client Relations at Larivière et Massicotte Pharmaciennes, talks about how their group is improving oncology patient care.

Mannar Dayoub

Tell us about the Larivière et Massicotte Pharmaciennes:

MD: Larivière et Massicotte Pharmaciennes, Inc., (LMP) is an independent Canadian pharmacy, based in Montreal, Quebec, dedicated exclusively to specialty medications. This means that we do not dispense any prescribed or over-the-counter medication other than specialty treatments.

Our main focus is in oncology

THE PATIENT IS AT THE HEART OF THE MISSION FOR THIS MONTREAL PHARMACY

treatment, which represents 70% of our clientele, but we also specialize in hepatitis, multiple sclerosis and cystic fibrosis treatments. Currently we have more than 10,000 patients on various specialty treatments.

LMP was founded in 2004 by Diane Bluteau, a former hospital pharmacist from Montreal. At the time, the business model was only oriented in supporting patients enrolled in patient support programs across the province of Quebec.

In 2015, LMP was bought by Christine Lariviere and Hélène Massicotte, a pharmacist duo from Montreal, who were convinced by the necessity and subsequent benefits that interdisciplinary collaboration was the future of the profession.

This vision led them to rethink and redesign the pharmacy's business model.

Assets of the old model included:

- A robust specialist network,
- A huge team of oncology experts,
- Excellent efficiency with the reimbursement processes,
- A renowned reputation for quality services,
- An ethical approach, and
- A good understanding of the needs of both patients and the pharmaceutical industry.

They worked with community pharmacists to upgrade this model and they implemented a reference/collaboration system to support rare and complex oncology treatments.

Today, LMP has a team of 17 pharmacists, 12 senior pharmacy technicians, four junior pharmacy technicians, a clerk, two receptionists, two accounting clerks and a pharmacy representative. We always have eight to 10 pharmacists on duty who offer white-glove service to patients, hospital teams and other stakeholders. We have 15 phone lines, and as a group, we speak eight different languages.

We are also involved with different patient associations as volunteers or

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speakers.

What are the main differences between oncology healthcare in the United States and Canada?

MD: In Canada, healthcare is regulated by each individual province or territory rather than a single federal health plan. Regular visits to doctors and hospitals, as well as diagnostic services are covered by Provincial Health Insurance. All prescription drugs provided in hospitals are covered publicly.

However, some services, such as dental and vision care, are excluded, though private insurance can cover these services.

In Quebec, patients who do not have access to private health insurance through their employers are eligible for public prescription drug funding. The funding is not a full coverage; patients have to pay a certain amount.

In the United States, healthcare plans are mostly provided through private companies and the American healthcare system is largely run without assistance from the government.

In certain circumstances though, the government acts as a safety net for those who are unemployed, are disabled (Medicare) or live at poverty level (Medicaid).

We've noticed a lot of similarities between Canada's health insurance system and the U.S. Medicare system.

Oncolytic treatment in Quebec usually requires prior authorization from the government as oncolytics are not listed in the standard drug list.

Physicians have to fill in special forms in order for the patient to have coverage for the drug (patient exception form or drug exception form).

This form must be completed regularly as the authorization is only granted for a restricted time (three to six months).

The paperwork is a challenge and can cause delays in the patient's treatment. Proactive coverage authorization follow-ups are therefore a necessity, and

In Quebec ... the patient remains free to choose the pharmacy of their choice, and insurance plans cannot direct a patient to a specific pharmacy.

this is where structured pharmacies like LMP become an asset in access and continuity of care for patients.

We employ two full-time experenced technicians that excel in navigating the complexities of the payer/reimbursement environment (public and private) and accelerate access to rare and expensive treatments.

One aspect of Quebec's system that differs from both the Canadian and American systems is patient's choice. The patient remains free to choose the pharmacy of their choice, and insurance plans cannot direct a patient to a specific pharmacy. Thus, validating the patient's consent is one of the first elements we confirm with the patient.

How do LMP pharmacists work with other members of your team to deliver high-quality patient care?

MD: We work in tandem with the community pharmacist (CP) in a unique way. Community pharmacists first discuss LMP's collaborative services and benefits. Once patient consent is obtained, the community pharmacy transfers the script. LMP then calls the CP to establish a systematic alignment once therapy has been initiated.

Needless to say, regular communication is critical to ensure that the community pharmacist remains aware of the patient's treatment as the CP will be orchestrating the patient's general medication.

LMP faxes an exchange summary form to the local pharmacy with updates on the patient's treatment whenever it is appropriate or needed. Ad hoc updates by phone or fax are required during the treatment.

In the same way, LMP extends coordination of care to oncology teams in hospitals and clinics. We provide personalized service tailored to the needs and practices of each facility.

Our team members also attend oncology conferences, congresses and volunteer activities, which provide them with the latest information in the field, as well as helps maintain their relationships with hospital oncology staff.

Internally, LMP commenced a Lean exercise/Kaizen in September 2018. This allowed us to completely reorganize and restructure all the procedures and processes to maximize the quality time spent by the pharmacists with patients, healthcare professionals and other stakeholders.

Going through the Kaizen process also afforded us the capacity to optimize production efficiency, which in turn provides a higher quality of life for employees at work. A weekly one-hour team meeting is also organized, to which everyone is invited and encouraged to share their best practices, and to brainstorm ideas for various aspects of our practice. These interactive meetings allow us to keep the Lean approach dynamic and alive.

To ensure the ongoing evolution of our specialty knowledge, our employees attend major international and regional conferences. We also organize in-house live sessions and actively participate in webinars.

What areas of your healthcare system could be improved upon?

MD: Quebec has had a public healthcare system, the Régie de l'assurance maladie du Québec (RAMQ), since the 1970s. For many years, negotiations

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PROVIDED PHOTO BY LARIVIÈRE ET MASSICOTTE PHARMACIENNE

Larivière et Massicotte Pharmaciennes has a team of 17 pharmacists, 12 senior pharmacy technicians, four junior pharmacy technicians, a clerk, two receptionists, two accounting clerks and a pharmacy representative.

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regarding pharmacists' honorariums between AQPP (the association of pharmacy owners) and the provincial government have stagnated, resulting in an honorarium fee today of roughly $9 per service.

The $9 service fee encompasses direct and indirect expenses related to the professional service and maintenance of pharmacy operations, including:

- Pharmaceutical evaluation (validation of the prescription, analysis of patient record and counseling services);
- Preparation and verification of medication;
- Professional responsibility for monitoring drug therapy throughout the course of treatment (lab analysis, patient profile analysis, adverse event monitoring, communications with healthcare professionals, patients and other stakeholders such as insurers); and
- Operating expenses to sustain the pharmacy's operations (salaries, rent, computer equipment, delivery, specialized devices, electricity, financial charges) to enable the delivery of a high-quality service that is readily accessible, including extended operating hours.

Pharmacists in Quebec are not allowed to accept any additional financial support besides professional fees already covered by the public or private insurance from pharmaceutical companies or program suppliers.

Approximately 35% of our oncology clientele is enrolled in a private insurance plan, which leaves about 65% who are covered by the public insurance regime (RAMQ).

Consequently, LMP must operate on a rigorously managed budget, but that has never stopped us from heavily investing in our employees to ensure that they have the necessary tools and knowledge to deliver professional services of the highest quality.

What are some projects within oncology that Larivière et Massicotte Pharmaciennes is working on currently?

MD: Our biggest endeavor is to develop a referral mindset in the community pharmacy environment. We strongly believe in offering the "family" pharmacist the option to refer their patient to a colleague, who has more experience in a specific therapeutic area, such as oncology.

We have a representative who visits local pharmacies, plus booths at major pharmacist and technician congresses.

We offer informational webinars and participate in panels discussing innovative development strategies for the community pharmacist.

We publish a monthly newsletter that summarizes the essentials of new oral oncology treatments, and many more.

Our message is simple: Larivière et Massicotte is a tool in the local pharmacist's toolbox. It represents a paradigm shift in the profession, but the Quebec political and professional environment is highly favorable to that model, and key stakeholders have already qualified our model as the practice of the future.

Another big project we are working on is in collaboration with the Question Pour Un Pharmacien (Ask Your Pharmacist) portal.

This web-based community was developed three years ago by a hospital pharmacist with the goal of offering patients valid and reliable answers to their questions.

Pharmacists across the province answer virtual patient questions in less than 24 hours, and some of our pharmacists participate as members. As it expands, the complexity of the questions from patients increases, spurring the need to offer consultations with expert pharmacists.

We will collaborate on a pilot project in February 2020, in which a fourth-year PharmD student from Université de Montréal will offer a premium consultation

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service in oncology under the supervision of our clinical team.

The goal is to test the benefit of modifying the existing local/regional Q&A structure to a provincial one – a modification that recognizes that developing expertise in oral oncology requires volume and rapidly reaches a plateau in a local/regional approach.

The results will be of utmost importance for the recognition of oncology expertise in the community.

One of NCODA's main goals is to improve upon the sustainability of patient care at the point of care, especially within the field of oral oncolytics. Where does LMP align with NCODA in this regard?

MD: The province of Quebec does not have dispensaries or medically integrated pharmacies, and has very few on-site pharmacies.

Larivière et Massicotte Pharmaciennes compensates for this by being very proactive and synchronized with the point-of-care (hospital/ clinic).

Needless to say, great communication is our key element and we are constantly working on ways to improve it.

Our team is on point and aware of the patients' blood tests, as well as their appointments with their physician.

No medication is dispensed before validating the blood work, or before having the physicians' approval for the next cycle.

This way, if a treatment is on hold or requires adjustments, we are advised with very little delay, thus avoiding the renewal of an inappropriate dosage or strength of medication, and thereby reducing cost and waste.

As the healthcare system in Canada is primarily supported by the government, waste avoidance is crucial, and the socio- and pharmaco-economic aspects cannot be ignored.

For physicians and other providers, access to the Quebec Health Record (QHR) is an essential tool for efficient and rigorous follow-ups (unless the patient chooses to be withdrawn from it).

Our team is on point and aware of the patients' blood tests, as well as their appointments with their physician. No medication is dispensed before validating the blood work, or before having the physicians' approval for the next cycle.

The QHR is a secure provincial tool that is used to collect and centralize information about the patient's health.

Professionals can obtain direct access to certain health information, such as lab results, imaging and medication dispense profile, regardless of the location of the patient or physician in Quebec.

One of NCODA's guiding values involves being "patient-centered." We have developed tools such as Oral Chemotherapy Education sheets and Treatment Support Kits to support this value. What areas does LMP see as ways both organizations can work together to help patients ?

MD: Patients are at the heart of our mission here at Larivière et Massicotte Pharmaciennes.

Many of our resources are deployed to ensure continuity of care and to avoid interruptions in treatment.

This is accomplished through proactive monitoring of insurance coverage, reaching out to the physician to ensure we have a valid prescription on hand before each renewal, and continuous monitoring of side effects (through structured touchpoints).

Our pharmacists follow the Direction Générale de Cancérologie (DGC) recommendation to spend 64 to 70 minutes per file for new patients, and 27 to 37 minutes to analyze each subsequent cycle prior to the dispense.

We ensure our patients have all the supporting therapies associated with their oncolytic drug and that they receive proper counseling on correct usage.

All patients also receive a symptom screening callback from a pharmacist five to seven days after initiating a treatment to help maintain the side effects at a Grade 1 or 2, and to avoid treatment interruption.

Our priority is giving patients all the tools at our disposal. This is why we are involved with NCODA's Treatment Support Kit committee

How does LMP see the oncology landscape and healthcare in general changing in Canada?

MD: The oncology environment in Canada is continuously improving to become better organized, with communities of practice exchanging protocols and tools to maximize system efficiency.

We are moving from an extremely fragmented infrastructure to a more centralized one, and the driving force behind this is to minimize costs as therapeutic options are rapidly evolving.

The province of Quebec is the most fragmented environment, with more than 50 centers active in oncology care. For a specialty pharmacy supporting patients from across the province, it requires a lot of agility to efficiently interact with these 50 different operating models.

In the future, we can expect the landscape to continue to set boundaries, drug utilization algorithms and reimbursement criteria.

For rare and expensive therapies, we foresee a more centralized coordination of care plan, with satellite hubs for care delivery.

In parallel, there is growing openness to public-private partnerships within the community, which could open great opportunities for a specialty pharmacy like ours.

▲ For information about Larivière et Massicotte Pharmaciennes, Inc., visit **www.lmpharmaciennes.com**. Follow LMP on LinkedIn **@Larivière-Massicotte-pharmacie-d'expertise**.

NCODA STRIVES TO ADD VALUE WHILE MEETING THE NEEDS OF OUR MEMBERS

Michael Reff

NCODA has launched several new initiatives to help oncology professionals establish and share best practices, as well as engage with both patients and fellow members.

It takes an extraordinary person to work in oncology, yet no one person alone can manage all the responsibilities required to provide effective treatment.

It takes a team effort to succeed. And time after time, team-based support has proven to be pivotal for providing improved patient care and optimal outcomes.

The team approach is a key reason why NCODA supports the Medically Integrated Pharmacy team in its quest to provide collaborative, patient-centered care.

To that end, we've launched several new initiatives to help oncology professionals establish and share best practices, as well as engage with both patients and fellow members:

▲ Our newly updated **Patient Satisfaction Survey** allows oncology practices to receive real-time feedback from their patients on how to better deliver continuous support.

▲ NCODA is collaborating with payers and national employer groups to create **NCODA Centers of Excellence**. The goal is to show how the centers and their Medically Integrated Pharmacy teams can provide high quality care and *Go Beyond the First Fill.*

▲ Our recent **Oncology Institute** provided thought-provoking and engaging discussion on current challenges faced by both oncology patients and practices. The event provided yet another platform for members to share insights with our industry partners, helping them better understand the needs of the practice and patient.

▲ On the academic front, **NCODA Professional Student Organization** chapters are springing up across the country, providing student pharmacists with the opportunity to collaborate with us while creating vital relationships with clinical oncology team members and industry professionals.

This educational initiative also offers student pharmacists the opportunity to participate in NCODA's **Advanced Pharmacy Practice Experiences** (APPE) elective rotation. Our college engagement initiative allows students to explore the world of oncology pharmacy and association management prior to graduation.

Our first APPE student-pharmacist, Rebecca Corvese (University of Rhode Island College of Pharmacy), rotated with us in the Fall of 2018. Her passion and commitment to NCODA led to her application and selection as NCODA's first **Oncology Association Management Fellow**. Over the course of her fellowship, Dr. Corvese will continue to work on projects that she began as a student.

▲ Our new print publication, ***Oncolytics Today***, continues to spotlight practices and members providing exceptional patient care across the country and around the world.

▲ In addition to all of this, I have some exciting news to share. NCODA and the American Society of Clinical Oncology (ASCO) are collaborating to develop **Oral Oncology Dispensing Standards** for enhancing the Quality Oncology Practice Initiative (QOPI) Certification program. This partnership has forged a committee of physicians, pharmacists, nurses, administrators and a patient to create a value proposition that will help change the standards for oral dispensing and lead to improved patient care.

Finally, NCODA members and partners are invited to join us at our annual **Fall Summit**, where you can learn more about empowering the medically integrated oncology practice.

NCODA's 2019 Fall Summit will take place Oct. 24-26 in Orlando, Florida. For two-and-a-half days, clinical experts, industry professionals, key stakeholders and hundreds of oncology care professionals will come together to examine the integrated dispensing model and discover methods of delivering high quality patient care. We hope to see you there!

Michael J. Reff, RPh, MBA
Executive Director and Founder of NCODA

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NCODA has partnered with Be The Match to save more lives since the beginning of 2017. Over that time NCODA has taken part in recruiting new life-saving Registry members and raised thousands of dollars to support the cause.

Join us in supporting Be The Match and their life-saving mission to make sure every patient finds their perfect blood stem cell match.

Would you like to host a recruitment drive or donate to Be The Match?

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Latrall, stem cell transplant recipient (left), with Raykell, her donor

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