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ION Solutions would like to recognize the members of our expert advisory panel who are bringing forth their experience, perspective and industry knowledge to better inform members about genomic and genetic testing.

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Center for Cancer and Blood Disorders

**James Gilmore, PharmD**  
Georgia Cancer Specialists

**Gary Grad, MD**  
Northwest Oncology & Hematology

**William Harwin, MD**  
Florida Cancer Specialists

**Natasha Khrystolubova, RPh**  
Florida Cancer Specialists

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Tyler Hematology-Oncology

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St. Louis Cancer Care

**Kashyap Patel, MD**  
Carolina Blood & Cancer Care Associates

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**Taral Patel, MD**  
Zangmeister Cancer Center

**Eileen Peng, PharmD**  
Regional Cancer Care Associates

**Nishan Tchekmedyian, MD**  
Pacific Shores Medical Group
# Table of Contents

**Summer 2019**

6  **Industry Insight**  
Foundation Medicine: Enabling Precision Medicine in Community Cancer Centers  
*An Interview with Brian Alexander, MD, MPH, Chief Medical Officer, Foundation Medicine*

12  **Case Study**  
The Importance of Precision Medicine Testing  
By Dr. Ralph Boccia and Dr. Kashyap Patel

18  **Overcoming Obstacles in Precision Medicine Testing**

22  **What’s News at ION**  
Why Your In-Office Dispensing Program Should be Accredited  
USP Issues Clarification on General Chapter <800>
One year ago, ION Solutions launched its web-based Precision Medicine Center, a resource that includes physician-developed guidelines for genetic and genomic testing. This library of clinical and operational recommendations helps you determine when and how to test appropriately and, ultimately, connect patients with the most effective personalized treatments. Because we understand there is a need for more education about precision medicine, we have dedicated this issue of Oncologistics to the subject.

Foundation Medicine is one of our genomic testing partners. The company’s portfolio of genomic profiling tests and molecular insights platform generate relevant information about patients’ cancers, contextualizing that information, and equipping researchers and drug developers with data and analytics to help advance precision medicine in cancer. Learn more from our conversation with Dr. Brian Alexander, Foundation Medicine’s chief medical officer, on page six.

In two case studies, Drs. Ralph Boccia and Kashyap Patel demonstrate how biomarker testing and next-generation sequencing have increased therapeutic options for patients with non-small cell lung cancer. These case studies illustrate the importance of precision medicine testing on page 12.

Precision medicine testing offers patients many benefits, however, there are implementation challenges for practices. Three members of ION’s Precision Medicine Advisory Panel discuss how their practices are overcoming obstacles on page 18.

Because precision medicine is an evolving field, it is important that we understand your testing practices so that we can continue to offer the services that deliver the most value. If you haven’t already, please visit the Precision Medicine Center on iononline.com and take the short survey regarding your practice’s current testing methods so that we can work with our partners to improve our offerings to you.

Thank you for your partnership.

Brian Ansay
President, ION Solutions

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All archived issues of Oncologistics are available online at www.iononline.com.
Foundation Medicine: Enabling Precision Medicine in Community Cancer Centers

An Interview with Brian Alexander, MD, MPH, Chief Medical Officer, Foundation Medicine
Foundation Medicine is a molecular information company dedicated to a transformation in cancer care in which treatment is informed by a deep understanding of the molecular changes that contribute to each patient’s unique cancer. The company’s full portfolio of comprehensive genomic profiling (CGP) tests and molecular insights platform aim to improve day-to-day care for patients by generating relevant information about their patients’ cancers, contextualizing that information, and equipping researchers and drug developers with data and analytics to help advance precision medicine in cancer.

ION Solutions recently spoke with Dr. Brian Alexander, Foundation Medicine’s chief medical officer and a practicing physician, about how precision medicine has the potential to revolutionize cancer care.

What developments in precision medicine are most exciting to you?

The more we learn about the molecular underpinnings of cancer, the more we’re realizing that cancer can be grouped by molecular biomarkers, including genomic signatures, not just the tissue of origin. This is evident by the fact that we have seen approvals of pan-tumor therapies that oncologists can prescribe based on a tumor’s genomic signature regardless of tissue of origin. Foundation Medicine continues to explore the role of pan-tumor biomarkers such as MSI and NTRK, which can be detected by our tests and now are associated with FDA-approved therapies. Additionally, we have led advancements in the clinical utility of tumor mutational burden (TMB) as a predictive genomic biomarker for response to immunotherapy. We are involved with numerous ongoing clinical studies with our biopharma partners including Bristol-Myers Squibb, Merck and Genentech to evaluate TMB as a predictive biomarker for response to immunotherapy across multiple tumor types.

Moreover, we are proud to participate in the research and development of therapies that target important biomarkers such as PIK3CA. Studies with alpelisib (PIQRAY®), a compound targeting this biomarker, showed promising results in patients with hormone receptor-positive/HER2-negative breast cancer and led to its recent FDA approval. Because our CGP panel is used so broadly, we were able to contact the physicians of thousands of patients who had undergone testing prior to this approval to alert them that there might be a new option. This speaks not only to the breadth and depth of the information that we generate, but also to our commitment to patients and their physicians to help facilitate the best treatment decisions possible, beyond just generating test results.

How is Foundation Medicine advancing the field of precision medicine in cancer care?

Cancer is a complex disease of the genome, and from my experience treating patients and leading Foundation Medicine’s medical team, I believe the more we understand cancer on a molecular level, the faster we can transform cancer care for patients. I’m excited to come to work every day because at Foundation Medicine, we’re uniquely positioned to leverage that understanding and knowledge to help patients and their physicians make the best treatment decisions possible and enable the development of powerful new therapies.

In 2010, we pioneered our breakthrough CGP approach to look inside an individual patient’s tumor to find clues about which treatment might be best for her specific cancer according to her unique genomic profile. Now, our tests analyze the tumors of thousands of patients each week, and we continue to expand our offerings. In addition to our testing portfolio, we also have one of the largest consolidated cancer genomic profiling databases in the country, FoundationCORE®, housing more than 300,000 cases, and the largest published clinico-genomic database (CGDB) in oncology, with more than 50,000 deidentified cases linked to treatment and outcomes data. Researchers can examine this database to help answer the countless questions that we all have about the molecular underpinnings of cancer, which have potential implications for the way we treat and advance cancer care for patients.
Liquid biopsy technology is another important development because it can open doors to CGP for patients who may not have tumor tissue available for testing or for whom biopsy may pose an unacceptable risk. This is particularly important for patients whose tumors are difficult to access, such as those with non-small cell lung cancer (NSCLC), where up to 30 percent of patients may not have adequate tissue available for standard CGP testing.

Currently only about 15 percent of people with advanced cancer are getting comprehensive genomic profiling, about 25 percent are receiving single maker testing and about 60 percent are getting no genomic testing at all. This means that many people with cancer and their doctors aren’t getting the information they need to make the most informed treatment decisions.¹

There is a lot of excitement about liquid biopsies. Where does FoundationOne Liquid fit in the treatment paradigm today?

We believe that determining a treatment plan for advanced solid tumors should start with CGP testing at diagnosis, whether it’s tissue-based or blood-based when tissue may not be the best option for the patients. Alternatively, there may be clinical situations where the liquid biopsy results may provide prognostic information but not lead to information to enable decision making. FoundationOne CDx and FoundationOne Liquid are important complementary tools and longitudinal reporting makes it possible to compare results over time, even if two different tests are used.

The next version of our liquid biopsy test received FDA breakthrough device designation and, if approved, could be the first FDA-approved liquid biopsy test to incorporate multiple companion diagnostics and multiple biomarkers to provide oncologists with a more complete view of their patients’ cancers.

What data did Foundation Medicine share at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting that you were really excited about?

At ASCO 2019, we presented data that further supports the utility of CGP to inform precision medicine in advanced cancer, including data on potential pan-tumor biomarkers FGFR and TMB. We were excited to share the results of a collaboration with Friends of Cancer Research to further characterize and harmonize TMB as a predictor of immunotherapy response. We also presented data in three subtypes of metastatic breast cancer analyzing the landscape of immunotherapy predictive biomarkers, including TMB.

What do you see as some of the biggest challenges in furthering the field of precision medicine?

Currently only about 15 percent of people with advanced cancer are getting comprehensive genomic profiling, about 25 percent are receiving single maker testing, and about 60 percent are getting no genomic testing at all. This means that many people with cancer and their doctors aren’t getting the information they need to make the most informed treatment decisions.¹ We are committed
to improving access and education around CGP so that those numbers can drastically improve. Our commitment extends to working in partnership with biopharma companies to develop new therapies, expand the number of FDA-approved therapies for which FoundationOne CDx can be used as a companion diagnostic and to accelerate collaborative research. We believe that CGP is an important component of a broadening set of cancer indications, and some cancer treatment guidelines are already suggesting broad molecular profiling. Without it, oncologists may not have the full information they would need to decide optimal therapy with the growing use of targeted agents and immunotherapies or match to clinical trials.

Another big challenge is how to make CGP test results as accessible and actionable as possible for clinicians. We’re addressing this challenge by giving clinicians the results of our CGP tests in a report which includes information and guidance on result interpretation as well as clinical and logistical support and are committed to improving the accessibility of our report as information continues to grow exponentially. Additionally, our Client Services and Medical Affairs teams have MDs and PhDs available to help oncologists make decisions that could transform patients’ lives. These experts also provide oncologists with a plethora of cancer genomics information such as thought leadership, publications, publication updates, monthly webinars and molecular tumor boards.

**Foundation Medicine has more than 60 relationships with biopharmaceutical partners. What solutions do you provide them?**

We recognize that collaboration is essential to accelerating our ability to help more patients today and in the future. We’ve long partnered with biopharmaceutical companies to discover and study new targets and help advance the development of new treatments. Our partnerships enable us to develop companion diagnostic tests that can determine patients’ eligibility for these personalized therapies.

Additionally, our partners benefit from FoundationCORE™, which I mentioned is the largest genomic profiling database in the U.S. with more than 300,000 cases and can be used to accelerate drug discovery and development. A partnership with Flatiron Health to integrate our world-class genomic data with their leading real-world clinical outcomes data led to the creation of the clinico-genomic database that I also mentioned. This novel database is continuously growing and is already being used by our research partners in both academia and biopharma R&D. We are particularly proud that this database predominantly comprises clinical outcomes from community oncology settings.

**How are you ensuring that all patients have access to CGP testing?**

Our CGP tests were designed to bring clinically relevant developments in cancer biology to patients everywhere, including in the community oncology setting. We have teams that support treating oncologists with interpretation of results, clinical and logistical information so oncologists can maximize understanding of the test’s results.

To support our patient-centric mission of advancing cancer care, Foundation Medicine is dedicated to reducing financial barriers that may keep patients from accessing our products, and we offer a financial assistance program to help patients navigate the insurance billing process and reduce the out-of-pocket costs for our tests.

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2019 Meeting Schedule

<table>
<thead>
<tr>
<th>Meeting Date</th>
<th>Meeting Name</th>
<th>Location</th>
<th>Venue</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 5-7</td>
<td>Precision Oncology</td>
<td>Austin, TX</td>
<td>Fairmont Austin</td>
</tr>
<tr>
<td>November 1-2</td>
<td>ION National</td>
<td>Phoenix, AZ</td>
<td>Sheraton Wild Horse</td>
</tr>
</tbody>
</table>

*Meeting Dates Subject to Change*

Registration will be available approximately 60 days prior to each event. To register, visit www.iononline.com.

A selection of videos and presentation slides delivered at ION meetings is available in the archives at www.iononline.com.
The Importance of Precision Medicine Testing

By Dr. Ralph Boccia and Dr. Kashyap Patel

This article identifies the importance of genomic testing in patients with non-small cell lung cancer (NSCLC) through the exploration of a pair of case studies. These case studies represent clinical and practical experience, discuss the use of biomarker testing and next-generation sequencing (NGS) and demonstrate how these advanced technologies have increased therapeutic options for patients with NSCLC.
Predictive Biomarker Testing in Non-Small Cell Lung Cancer

A 27-year-old student from India pursuing a doctorate in economics at the University of Oxford in England developed a progressive cough, shortness of breath and weight loss. He went to his general practitioner in England and initially received a course of antibiotics (Azithromycin) without much relief. He continued to lose weight and started developing cachexia.

At the time, his chest X-ray revealed bilateral multiple nodular lesions and a large 3.5x4 cm lesion in the right lung. He was started on anti-tuberculosis treatment with empirical diagnosis for several weeks. His condition continued to worsen. After eight weeks of treatment he developed hemoptysis and orthopnea. He was hospitalized in early July 2017 in the United Kingdom. His scans revealed worsening lesions, multiple liver as well as bilateral adrenal lesions. He needed 2–3 liters of oxygen continuously.

He underwent a biopsy of the index lesion that revealed adenocarcinoma. His NGS cancer panel (NHS protocol for cancer panel) included EGFR, BRAF, TP53, PTEN, PIK3CA, PDGFRA, NRAS and KRAS. Given his worsening condition, he was airlifted to join his parents in India with a diagnosis of terminal lung cancer and possible referral for comfort and hospice care. At this juncture his family reached out to Carolina Blood and Cancer Care in the U.S. We started coordinating with his oncologist in India.

We requested further workup on his tumor including EGFR, ALK, ROS, Met and PD-L 1.

His tumor was negative for EGFR. However, it was positive for ALK (D5F3) using immunohistochemistry (IHC) and PD-L 1 was 100 percent.

By this time, he had received one cycle of pemetrexed carboplatin and Bevacizimab in India. We decided to start him on Alectinib.

Within four weeks of initiating treatment with Alectinib, his performance status improved, and he started walking with ambulatory oxygen. Within eight weeks of starting treatment, he started walking one mile daily and resumed his studies remotely.

His follow-up CT scan in January 2018 revealed near complete resolution of all liver metastases and adrenal metastases. His lung lesions also resolved.

In December 2018, he completed his thesis for his doctorate degree and got married. In March 2019, his scans confirmed no evidence of disease. Apart from mild elevation of his liver function tests, all blood work was also negative. He runs 3–4 kilometers every day, works full time in India and is enjoying married life.

Precision medicine is the most promising field for the hope of achieving better and longer survival while also reducing side effects from treatment.

Next-Generation Sequencing in Metastatic Non-Small Cell Lung Cancer

A 73-year-old white male, ex-smoker presented with cough in October 2015. A chest X-ray showed a 4 cm right upper lobe (RUL) mass. CT scan showed a large RUL mass and mediastinal adenopathy. No distant disease was seen on imaging. Brain MRI was negative. A mediastinoscopy and biopsy was performed and confirmed adenocarcinoma.

He was considered Stage IIIA and was started on thoracic radiation therapy and weekly Carboplatin/Paclitaxel. He tolerated systemic treatment poorly and did not complete a full course of chemotherapy. He did complete radiation therapy to 63 cGy.

The patient recovered very slowly. A follow-up PET/CT scan in June 2016 showed progression in the primary lesion, mediastinal and hilar nodes. MRI showed a new right frontal brain metastases. PDL-1 was >1%. He received Cyberknife treatment to the brain lesion and started Nivolumab. The brain met disappeared. His thoracic disease responded with a partial response during the treatment from July 2016 through December 2017. Progression in the chest was then documented on a CT scan. Brain MRI remained negative. His performance status is normal (ECOG 0), and he enjoys normal activities and lifestyle.
Discussion

The National Institutes of Health (NIH) defines precision medicine as “an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment and lifestyle for each person.” However, there is also a school of thought that exhibits cautious optimism. According to Dr. George Sledge, FASCO, past president of the American Society of Clinical Oncology (ASCO), “Precision medicine is not a panacea; it’s a tool. And like all tools, it needs to be used appropriately.”

The enthusiasm around precision medicine and personalized medicine is worth pursuing and researching further. With more than 50 percent of all drugs being developed for cancer treatment having some type of companion diagnostic as a part of studies being explored, biomarkers are stratifying almost 90 percent of patients in current clinical trials.

There are multiple success stories around precision medicine from the days of ER/PR and HER 2 positivity to ALK, EGFR, ROS, Mets, TRK and other tumor markers in solid tumors. The BCR/ABL target in CML where we have close to a “magic bullet.” Even in hematological malignancies, we have seen encouraging results incorporating precision medicine therapies in IDH 1 and 2 mutations in AML. There are some disappointing results too. For example, Vadastuximab talirine for AML and MDS, Tarextumab for SCLC and Prophage G-200 for glioblastoma. Some targeted therapies (EGFR and ALK) can now render complete response in some patients with NSCLC with brain metastasis eliminating or delaying the need for brain radiation.

Further, the NIH/NCI (National Cancer Institute) aggressively support the basket trials given the belief that the future is in targeted, precision medicine, rather than the old shotgun approach, and the mixing of known, older drugs desperately searching for better outcomes.

Precision medicine presents various opportunities.

- Improves outcomes
- Identifies driver mutation with actionable options
- Provides an alternative to the conventional approach, which fails in 75 percent of patients with advanced solid tumors, resulting in both financial and physical toxicities
- Has improved survival from two years in advanced melanoma to 16 years in BCR-ABL positive CML
- Avoids ineffective treatment both in terms of cost and side effects
- Advances science. Molecular testing is now the fastest growing segment of the U.S. laboratory market.

However, there are challenges as well.
- Wide variance in test offerings
- Lack of standardization
- Lack of clinical utility correlation
- Reimbursement guidelines for coverage not established
- Lack of integration of pharmacogenomics, personalized medicine and payer and regulatory pathways for test approval
- Need for education of providers, payers, pathologists and other stakeholders
- Spending is difficult to predict; currently accounting for 10 percent of all lab spending and increasing 15–20 percent annually
- Total genetic testing costs projected to reach $15–20 billion by 2021

In summary, precision medicine is the most promising field for the hope of achieving better and longer survival while also reducing side effects from treatment. We are at the cusp of a paradigm shift with scientific discoveries that will offer optimism and hope for even stage IV cancer patients that were once doomed to short survival and early death.

About the Authors

Ralph Boccia, MD, is Clinical Associate Professor of Medicine at Georgetown University in Washington, DC, and Director of the Center for Cancer and Blood Disorders in Bethesda, Md. He is also Chief Medical Officer for ION Solutions and Oncology Medical Director for the clinical research organization (CRO) Accelovance. Dr. Boccia earned a medical degree at the University of Minnesota and completed training in internal medicine at University of California, Los Angeles (UCLA)–affiliated hospitals. His hematology, oncology and bone marrow transplant fellowships were completed at the combined UCLA-VA Program and The National Cancer Institute at the National Institutes of Health in Bethesda, Md. He is a member of many professional societies including the American College of Physicians, American Society of Clinical Oncology, American Society of Hematology and the American Society for Blood and Marrow Transplantation. With his vast experience and research, Dr. Boccia has published numerous articles in the Journal of Clinical Oncology, New England Journal of Medicine, British Journal of Hematology, Cancer, Blood, Annals of Internal Medicine, Lancet and Oncology. He is listed in Who’s Who in America, has been voted into Washingtonian’s Best Physicians in Washington, is listed in Best Physicians in America, and Consumers’ Checkbook’s Guide to Top Doctors in Washington, DC, every year since 1992.

Kashyap Patel, MD, is the CEO of Carolina Blood and Cancer Care Associates. Dr. Patel is a full-time practicing medical oncologist, board certified in Hematology, Oncology and Internal Medicine. He is also serving as a vice president for the Community Oncology Alliance (COA) and Medical Director for ION Solutions. He is a chair-elect for clinical affairs for the Association of Community Cancer Centers (ACCC). He is also a member of the CPC committee for the ASCO and National Committee for Quality Assurance (NCQA). He has been an advisor for the large payers including DHHS (SC) and Palmetto GBA. He also serves on an advisory board for Medicaid HMOs. Dr. Patel is past president of the South Carolina Oncology Society. He has had extensive research experience in the field of oncology and has published and presented articles in journals nationally and internationally.
The ION Solutions Precision Medicine Center is your gateway to a single, centralized library of precision medicine testing recommendations and resources. Access all of the testing recommendations created by our physician- and pharmacist-based advisory panel as well as resources curated by ION Solutions and our precision medicine partners to help you make informed decisions for your patients.

View testing recommendations by tumor categories:
- Breast Cancer
- NSCLC
- Colorectal
- Genitourinary
- Lymphoma
- Rare Disease
- Multiple Myeloma
- Leukemia

As precision medicine continues to evolve, ION will continue to provide the tools your practice needs.

Visit IONonline.com/Precision to learn more.
Precision Medicine Center

The ION Solutions Precision Medicine Center is your gateway to a single, centralized library of precision medicine testing recommendations and resources. Access all of the testing recommendations created by our physician- and pharmacist-based advisory panel as well as resources curated by ION Solutions and our precision medicine partners to help you make informed decisions for your patients.

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As precision medicine continues to evolve, ION will continue to provide the tools your practice needs.
Overcoming Obstacles in Precision Medicine Testing
Genetic, genomic and biomarker tests are transforming cancer care and treatment. However, the development and diffusion of gene expression profiling and next generation sequencing tests have out-paced the generation of data on their clinical utility and the development of clinical guidelines.¹

The increasing use of genetic, genomic and biomarker tests in oncology identifies the need for recognition of validated testing, testing approved by the Food and Drug Administration (FDA) and reimbursed by payers, consistency in terminology, and education for both providers and patients. As more oncology providers consider the use of genomic testing to help inform treatment recommendations, many are identifying barriers to their use.

In 2018, ION Solutions launched its Precision Medicine Testing Recommendations developed by a Precision Medicine Advisory Panel made up of oncologists, pharmacists, nurses and research experts. Eileen Peng, PharmD, of Regional Cancer Center Associates, is a member of ION’s Precision Medicine Advisory Panel.

“We are working toward a bigger outcome picture,” says Peng who serves as both practice administrator and pharmacy manager for the network in New Jersey. “It is critical for practices to have an efficient precision medicine/genomic testing workflow to ensure that appropriate treatment plans are being chosen for patients.”

Peng and her colleagues on the panel, James Gilmore, PharmD, Executive Vice President of Georgia Cancer Specialists, and Natasha Khrystolubova, RPh, BPharm, BCOP, Associate Director of Pharmacy Clinical Services of Rx To Go Oral Oncology Pharmacy of Florida Cancer Specialists & Research Institute, have identified a number of barriers that they are trying to address. The identification of the appropriate tests and the mechanism for ordering tests top the list.

Some companies require online ordering through their own web portals, others create a form, and the methods (tissue versus liquid biopsy) can also vary. Gilmore noted that “practices can also often experience challenges associated with some of the logistical processes delaying access to tissue, and the amount of tissue needed for testing.” Depending on the testing company, follow-up with results can take days or weeks.

Each of these practices has worked diligently to streamline their internal workflow processes, identifying specific testing companies, ensuring the tests have FDA approval for potentially easier reimbursement and helping the providers understand which test might be most appropriate, although providers make decisions on testing themselves.

Another challenge is the testing report, as providers may need to interpret the results. “It is not always clear if the description means a fusion or a mutation; and this can be quite important when we talk about NTRK (neurotrophic-tropomyosin receptor kinase) fusions and the agent on the market to treat cancers with the fusion, not a mutation,” said Khrystolubova. She also provided an example of a result when an off-label prescription was turned down by a payer due to a “median-level MET amplification” finding instead of a “high-level MET amplification” that could have granted an approval for an off-label use of crizotinib in non-small cell lung cancer.

Without consistent terminology across tests, providers are often tasked with interpreting results and researching for literature that helps support the use during the prior
authorization process. Each of the practices has been fortunate to create a searchable database with next-generation sequencing (NGS) reports, doctors’ notes, including sortable information about specific tumor characteristics, and evidence-based publications for their patients. “This information should be able to be stored in a user-friendly way in our EHRs. Our goal is to be able to integrate these results in an automated way across the practice,” says Gilmore. Each of the panelists identified the need for the creation of a nationally available database to help support research, identify patients for clinical trials and provide evidence to support off-label treatments for the patients’ insurers or to find assistance in the free drug application process.

Internally, the practices can identify patients with specific mutations, identify treatment plans and also find those specific patients who may be candidates for highly specific clinic trials based on genomic information. Yet there are still issues when a test is initially ordered by a larger health system and treatment recommendations are made to the community oncologist. Often the full test results and notes are not available for use when securing the prior authorization.

The call for the shared digital library may eventually drive EMR vendors and genomic testing companies to look for standardization across platforms. As processes are streamlined and guidelines are developed for all practices, there is a need for increased education on both the provider side as well as the patient.

As of May 2017, there were approximately 75,000 genetic tests on the market, with about ten new tests entering the market daily. Multi-gene panels number close to 10,000. The challenge for the oncology practice is understanding the test, its validation methods and insurance coverage for the patient.

“While we (pharmacists) are not ordering tests needed for making treatment decisions, we can play an important role in assisting our patients with understanding the importance of the tests and finding financial assistance to lessen burdens on patients. Tests that are not approved by the FDA or reimbursed by the payer can place the patient at serious financial risk,” says Peng.

Gilmore concurs, “From a management perspective, it is very important to understand that these tests are very expensive, and the patients may be required to bear a significant portion of these costs. Since most of this testing is done outside of a typical community oncology practice and patient coverage varies, we often don’t know exactly what these costs will be when we order them. We still need to ensure that the patients are informed of their potential costs.”

In addition, education for those patients is necessary so they understand the potential timing of return of test results, and what they as a patient need to do with the information, for example with BRCA1 and BRCA2 tests showing inherited gene mutations.

The goal of these Precision Medicine Panel members is to help providers establish testing recommendations across the country – for small and large practices. The goal of these Precision Medicine Panel members is to help providers establish testing recommendations across the country – for small and large practices. All while understanding the information and data required to make the process of prior authorization go more smoothly, reducing the burden placed on the patients.

“Creating this Precision Medicine Panel has been very forward thinking because we are seeing a huge increase in testing across ION practices. This development of recommendations, even outside of the ION practices, needs to be addressed at a much higher level,” concluded Khrystolubova.

2. Genetic Test Availability And Spending: Where Are We Now? Where Are We Going? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5987210/
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Why Your In-Office Dispensing Program Should be Accredited

As oncology providers see an increasing benefit to dispensing medications directly to patients, especially with the rise in oral oncolytics, the practice is also tasked with maintaining high levels of standards to stay in the narrow networks of payers or pharmacy benefit managers. Those levels of standards are often regulated by receiving accreditation from one or more of the national accrediting organizations, like the Accreditation Commission for Health Care (ACHC) and URAC.

On its website, ACHC states that accredited pharmacies “demonstrate their commitment to providing the highest-quality service through compliance with national regulations and industry best practices.”

The standards created by the accreditation organizations drive the quality of care delivered by providers. The practice often needs to submit data on how it is measuring the quality of its services, including data generated from quality measures in the Centers for Medicare & Medicaid Services (CMS) Quality Payment Program.

Not being allowed to stay in a network could not only make a significant financial difference to the practice, but also affect how providers can maintain more oversight into a patient’s care. Accredited practices are in a better position to manage future requirements from payers; and with quality improvements, practices typically see organizational costs decrease.

The pharmacy team at ION Solutions can help your practice stay in payer networks so you can increase patient convenience and improve outcomes by dispensing oral oncolytics. The team’s services may include assisting with ACHC accreditation, URAC accreditation or other accreditations necessary for staying in payer networks.

Throughout the accreditation process, the team, made up of pharmacy consultants and pharmacy tech consultants, will review policies and procedures and documentation of compliance to those policies or procedures. The team also is available for pre-survey visits and can be at your practice the day of the on-site survey to provide support to the practice staff. The team may also conduct mock inspections to ensure your practice is ready.

For more information or to talk to one of the consultants about pharmacy accreditation, contact SON@iononline.com

Please note: ION Solutions does not endorse any specific accrediting agency, but uses the ones mentioned above as examples.

USP Issues Clarification on General Chapter <800>

Specialty practices have been preparing for USP General Chapter <800>, the standard on the safe handling of hazardous drugs, to go into effect on Dec. 1, 2019. However, in a recent clarification, the United States Pharmacopeia (USP) stated that because USP <800> is cross-referenced to the standards that only pertain to compounded drugs (<795> and <797>) the changes under <800> may not apply to specialty practices that only handle hazardous drugs.

The USP <800>-final standards are more closely aligned with the Food and Drug Administration’s (FDA) definition of compounding, making activities such as the administration of a sterile medication and the preparation of drugs (mixing, reconstituting and other acts) not subject to the compounding standards in <797>.

Enforcement of USP standards is the responsibility of the FDA, state governing bodies and other regulatory authorities. USP has no role in enforcement. Because USP <800> can be utilized in healthcare settings beyond compounding at the discretion of regulatory authorities and other oversight organizations, your practice should contact your state governing body (pharmacy board, regulatory agency, accrediting organization, etc.) regarding compliance guidelines.

USP <800> is designed to protect both your patients and staff from potentially hazardous exposures. Regardless of this clarification, practices should still consider following the guidelines for Personal Protective Equipment (PPE) and Closed System Drug-Transfer Devices (CSTD).

For more information on the clarification or how it may affect your practice, send an email to consulting@iononline.com.
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