

Cardinal Health Specialty Solutions

Oncology Insights:

June 2018

Views on Precision Medicine and Genomic Testing Practices
From Specialty Physicians Nationwide





A message from the President

Joe DePinto

Welcome to the third edition of *Oncology Insights*, the latest in our series of research-based reports providing insights on issues of importance to specialty care providers, biopharma companies and other healthcare stakeholders.

The theme of the 2018 American Society of Clinical Oncology (ASCO) conference is “Delivering Discoveries: Expanding the Reach of Precision Medicine.” This is fitting in a year when the oncology community is buzzing about the potential for precision medicines to dramatically advance oncology care. In just the past year, we’ve seen the FDA approval of two CAR-T therapies for blood cancers, the approval of a PD-1 inhibitor for MSI high tumors regardless of origin, and targeted medicines for acute myeloid leukemia, bladder, ovarian, breast and lung cancers.

While many precision medicines have exciting potential, clinical data alone won’t be enough to determine commercial success. We aimed to better understand how physicians perceive precision medicines and their impact on oncology care. Through our Specialty Solutions Summits, we conducted research with more than 160 oncologists at Cardinal Health Oncology Summits earlier this year. We explored their perceptions about new therapies and possible barriers to adoption. We also looked at availability of genomic testing and how testing is impacting diagnosis and treatment. The responses provide an insightful view into how precision medicine is beginning to reshape oncology care.

We hope you find this report valuable in advancing constructive dialogue across our industry.

Sincerely,

Joe DePinto
President, Cardinal Health Specialty Solutions



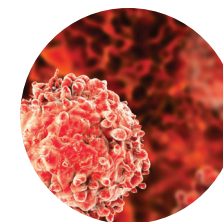
Precision Medicine: Promising Therapies and Complex Challenges

Defined by the National Institutes of Health as a “form of medicine that uses information about a person’s genes, proteins and environment to prevent, diagnose and treat disease,” precision medicine is poised to open the door to a new era of cancer care.

From immunotherapies that stimulate the immune system to help the body fight disease, to therapies that target specific molecular drivers involved in disease growth, to gene therapies that introduce genetic material into cells to compensate for abnormal or mutated genes, these innovative products are turning what was once science fiction into science fact.

The potential impact on oncology care is significant, particularly for types of cancer that have a genetic underpinning. But the impact won’t be limited to cancer. Treatment for more than 7,000 inheritable genetic disorders may be dramatically improved in the coming years as result of precision medicine research. Last year, the FDA approved Luxturna™, a gene therapy for a rare form of blindness, which was the first therapeutic for an inherited disease. Many more products are in the pipeline, including potential advancements for diseases like sickle cell anemia, hemophilia and muscular dystrophy.

While these innovative therapies are delivering new hope for patients and healthcare providers, they also bring complex challenges. Most of these therapies will be very expensive and stakeholders will undoubtedly engage in intense debate about how to calculate their value, which patients should receive them, and how to pay for them. These are just a few of the issues we touch upon in our recent research with oncologists.





OUR VIEWPOINT

Bruce Feinberg, DO

Vice President and Chief Medical Officer

Precision Medicine: New Possibilities and Greater Complexities

The foundational concepts of precision medicine, which have roots dating back to the discovery of the Philadelphia chromosome in 1960, could not be fully realized until the past decade with the commercialization of proteomic and genomic analytics. That history and the early clinical outcomes data suggest that precision medicine is more than the buzzword of the moment – it is the start of a new era in oncology care. Our research shows that many oncologists agree – nearly 40 percent said they see precision medicine as a potentially game-changing approach to treatment that will likely cure certain chronic and life-threatening diseases.

Although only about 10 percent of malignancies are currently treated using targeted or gene therapies, that number is likely to rise exponentially in the coming years, as reflected by 41 percent of our survey participants who said they expect a large portion of oncology patients will be treated with precision medicines in the next two to three years. However, the added complexity of patient selection and treatment decision-making will pose new challenges for all healthcare stakeholders.

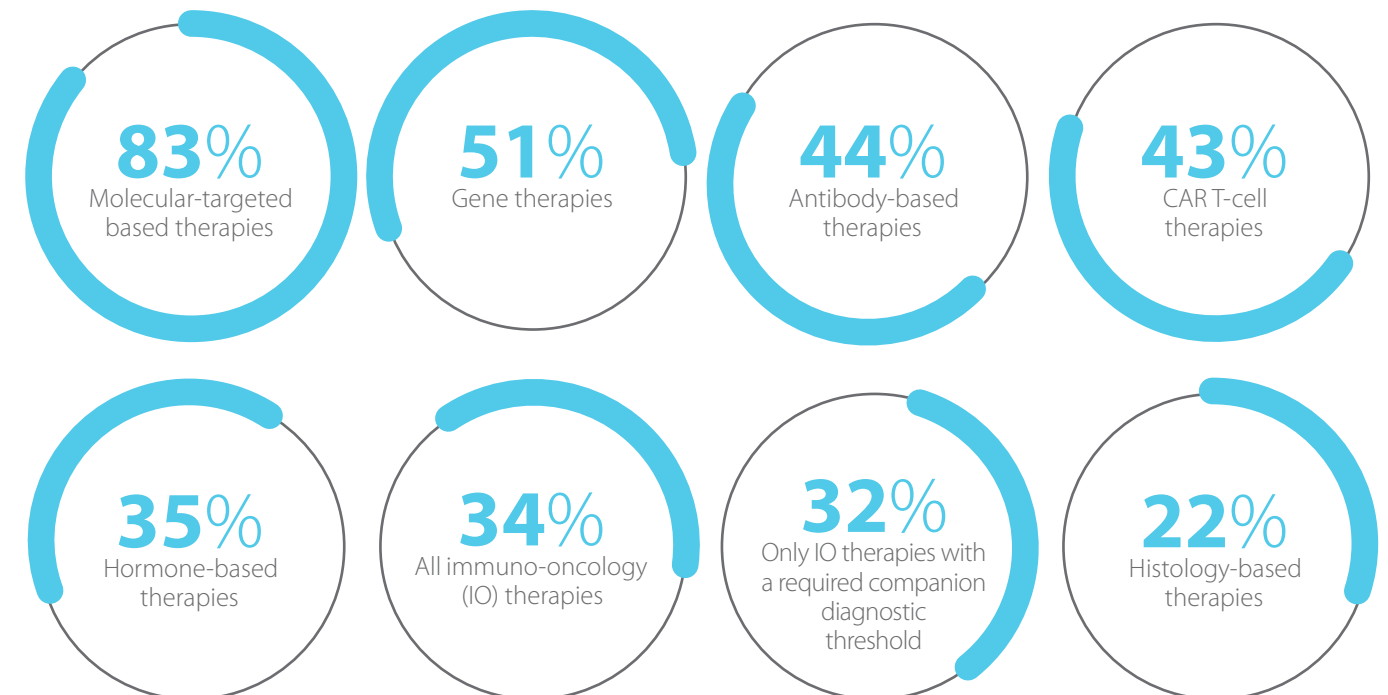
Cost is gradually eclipsing efficacy and toxicity in the value determination equation. As our research shows, whether it is the actual cost of a therapeutic, the patient responsibility, or the margins and fees for the administering provider, cost seems to be the elephant in the room for nearly 60 percent of providers. While this issue is unlikely to be resolved in the near term, we can expect to see more outcomes-based reimbursement contracts with payers, where the manufacturers only receive payment for the product if the patient achieves certain clinical milestones, as well as long-term leasing contracts, where reimbursement is spread out over months or even years depending on the duration of the patient's response. We should also expect continued investment by manufacturers in programs to help alleviate the financial burdens on patients. Our research shows that 76 percent of participating oncologists view this as the resource that is most needed as more precision medicines come to market.

PRECISION MEDICINE

The term “precision medicine” means different things to different oncologists, but most agree that it includes molecular-targeted based therapies.

The diversity of responses demonstrates that the industry has not come to a clear consensus on what types of therapies comprise precision medicine.

In your opinion, which of the following constitutes “precision medicine?” (select all that apply)



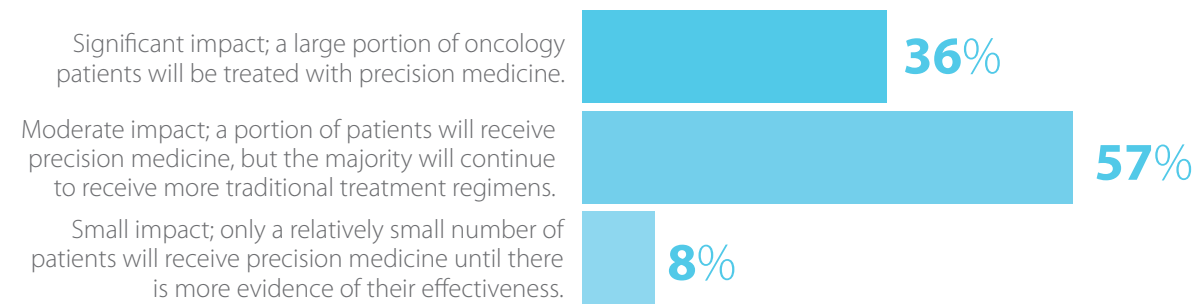
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DESPITE THE PERSONALIZED NATURE OF **CART-CELL THERAPIES**, ONLY

43% SAID THEY CONSTITUTE PRECISION MEDICINE.

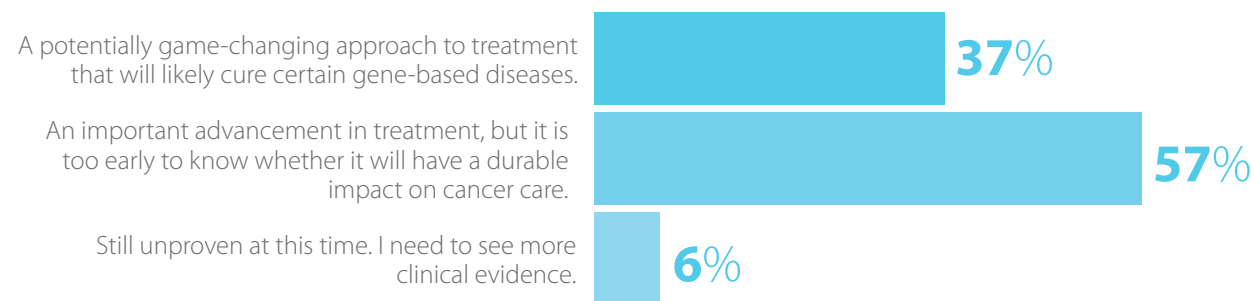
While oncologists generally think it's too soon to tell whether precision medicine will have a long-term impact on cancer care, more than one-third see it having a significant impact in the next two to three years.

Looking ahead, how do you see precision medicine impacting oncology care over the next 2 – 3 years?



N=143

How would you best describe precision medicine?



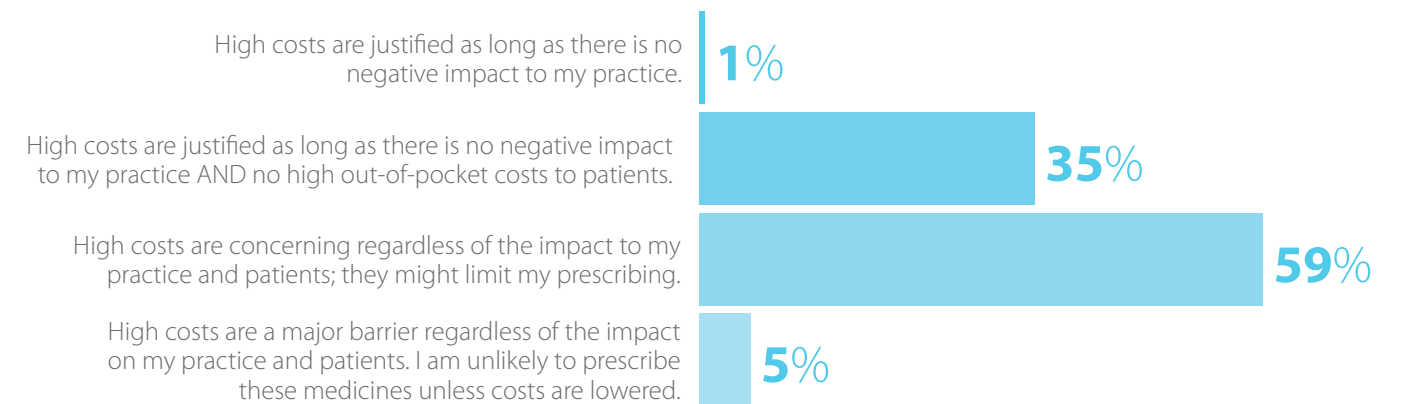
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NEARLY **4 in 10** } ONCOLOGISTS SAID PRECISION MEDICINE IS A **POTENTIAL GAME CHANGER FOR CANCER TREATMENT.**

Cost of treatment is seen as the primary barrier to wider adoption.

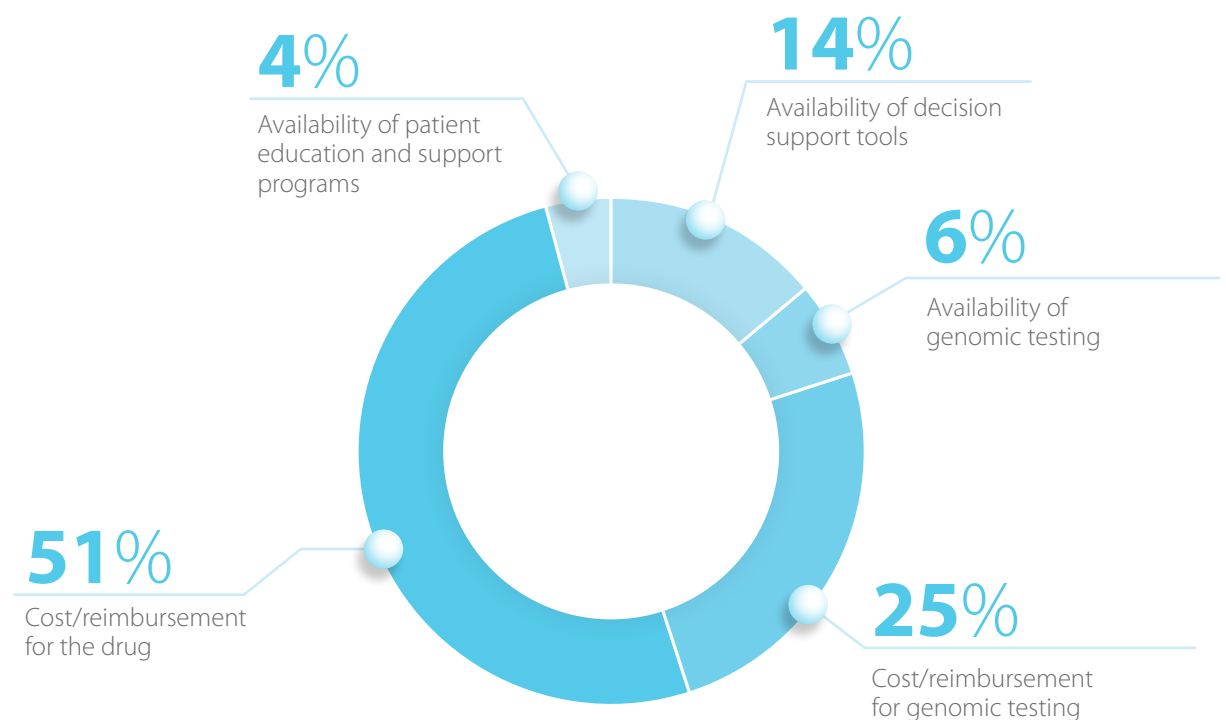
Concerns about the high cost of precision medicines persist even when there is no direct impact on patients or their practices.

Assuming the efficacy data for precision medicine is strong, which of the following best describes your perception about costs?



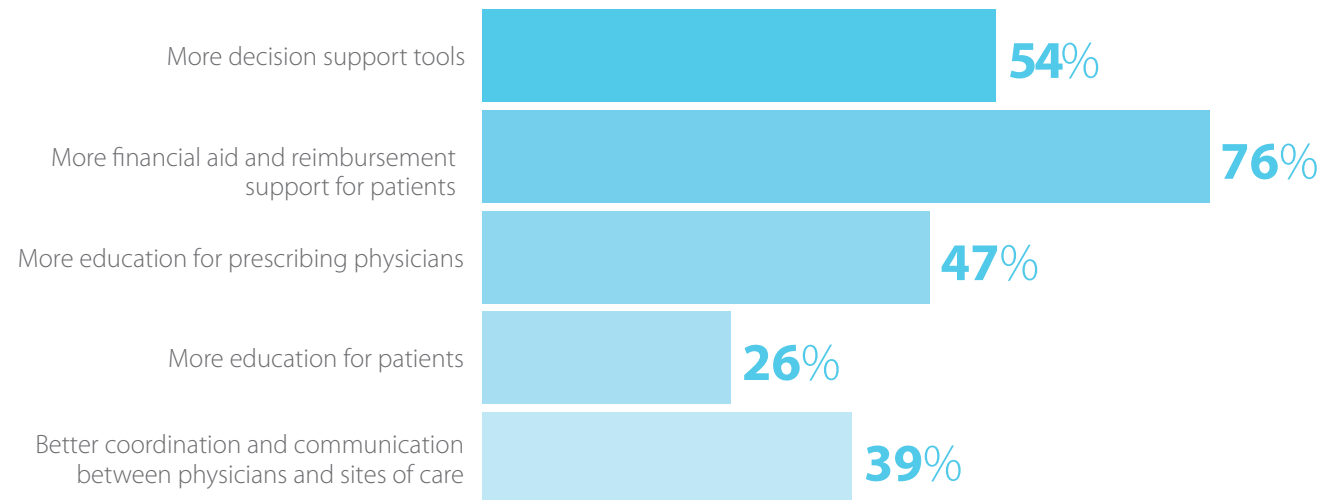
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What are the biggest barriers to the adoption of precision medicines?



N=148

As more precision medicines come to market, what additional resources are needed?
(select all that apply)



N=147

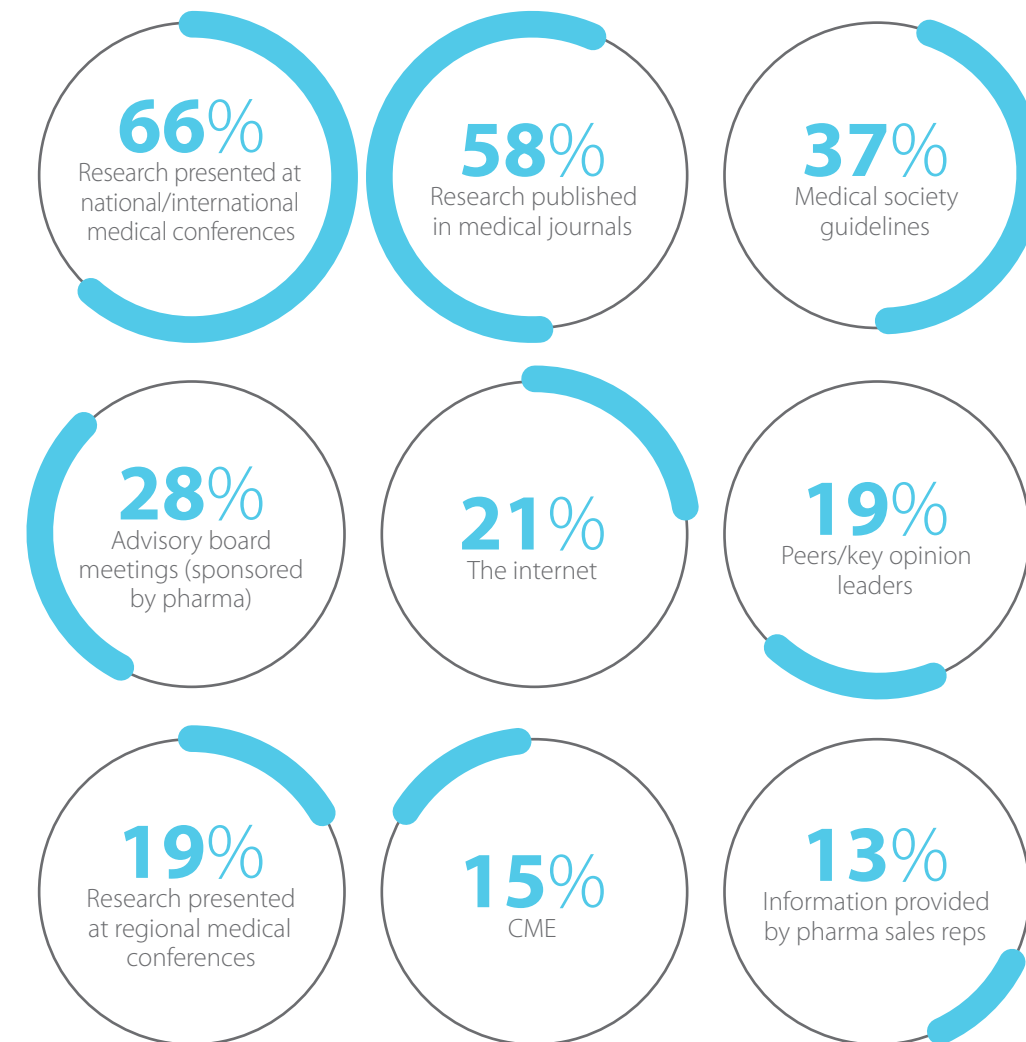


MORE THAN 75% OF PARTICIPATING ONCOLOGISTS SAID **MORE FINANCIAL AID AND REIMBURSEMENT SUPPORT** FOR PATIENTS ARE NEEDED TO PROMOTE WIDER USE OF PRECISION MEDICINE.



While oncologists primarily learn about precision medicine from research presented at conferences and in medical journals, more than 20 percent also rely on less traditional sources such as the internet and advisory board meetings sponsored by pharma.

What tools and resources do you rely on most to learn about new precision medicines as they come to market? (select the top three)



N=149

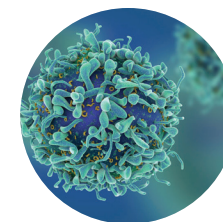
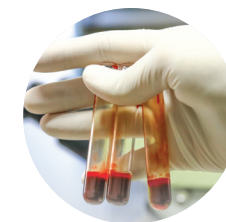
NEARLY **3 in 10** } PARTICIPATING ONCOLOGISTS RELY ON **PHARMA-SPONSORED ADVISORY BOARD MEETINGS.**

Role of Genomic Testing in Precision Medicine

The ability to easily and cost-effectively identify patients who can benefit from precision medicines is central to the question of whether they will be widely adopted.

According to the Centers for Disease Control and Prevention (CDC), genomic testing can be used to look for single genes that are associated with inherited genetic disorders; identify mutations in otherwise protective genes that may be responsible for certain hereditary cancers; and look for genes that may increase a patient's risk of developing certain diseases. They can also be used to help identify genetic variations that can influence a person's response to medicines.¹

While these genomic tests have substantial potential to enable more personalized care, the practice of using them routinely in diagnosis is still new and quite complex. There are literally thousands of genomic tests available today in the United States,² yet very little education or resources to help providers know which ones to use. What testing should be performed, when, at what frequency, how will it be interpreted, by whom, what criteria will be used to select treatment, and who will pay for it all represent significant challenges for patients, providers, payers and manufacturers. In our research with oncologists, we explored some of these issues and looked at how genomic tests are being used today.





OUR VIEWPOINT

Chadi Nabhan, MD, MBA, FACP

Vice President and Chief Medical Officer

Genomic Testing – The Key to Identifying Precision Care Patients

With more precision oncology drugs available, oncologists have grown more dependent on genomic tests to diagnose and treat various malignancies. In fact, 97 percent of surveyed oncologists stated that genomic testing is either somewhat or very important in diagnosing and treating cancers. While not every treatment requires genomic testing, 23 percent of respondents suggested they will use genomic/mutational testing in the coming year.

As more precision medicines come to market, hospitals and healthcare systems will need to be cognizant of the need to have these tests available with favorable turnaround times that allow for timely administration of therapies. Unfortunately, 26 percent of physicians stated that such tests are not available locally today and when sent to an outside vendor, results are delayed beyond 15 days. These delays could have therapeutic implications and create barriers that need to be looked at carefully.

In addition to availability issues, many participating physicians said payers' failure to cover the costs of these tests stood out as a common barrier to adoption of genomic testing. Almost all respondents stated that preauthorization is needed when ordering these tests — and many said out-of-pocket costs to patients was a barrier, although this clearly varies by region and insurance coverage.

Understanding the output of genomic tests is critical and interpreting them is a challenge — as demonstrated by the 59 percent of oncologists who reported challenges in understanding the results. Clearly, this highlights an educational opportunity for manufacturers and academic physicians.

While use of genomic testing will certainly continue to grow as more precision medicines come to market, understanding barriers to uptake and cost implications will be essential to assure patient access.

GENOMIC TESTING

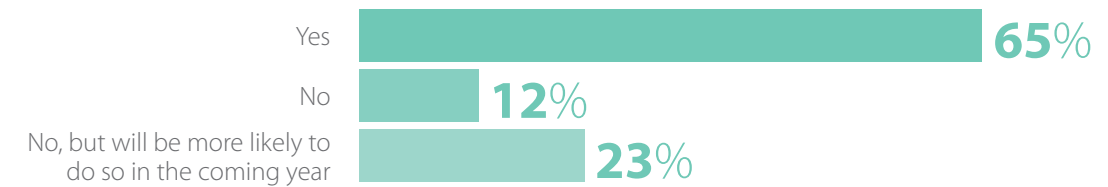
Genomic testing is widely viewed as “very important” in diagnosing and treating cancer patients, and its use is expected to grow in the coming year.

How important is genomic testing in effectively diagnosing and treating patients with cancer?



N=145

Do you routinely use genomic testing on your patients in order to determine an appropriate or ideal therapy?



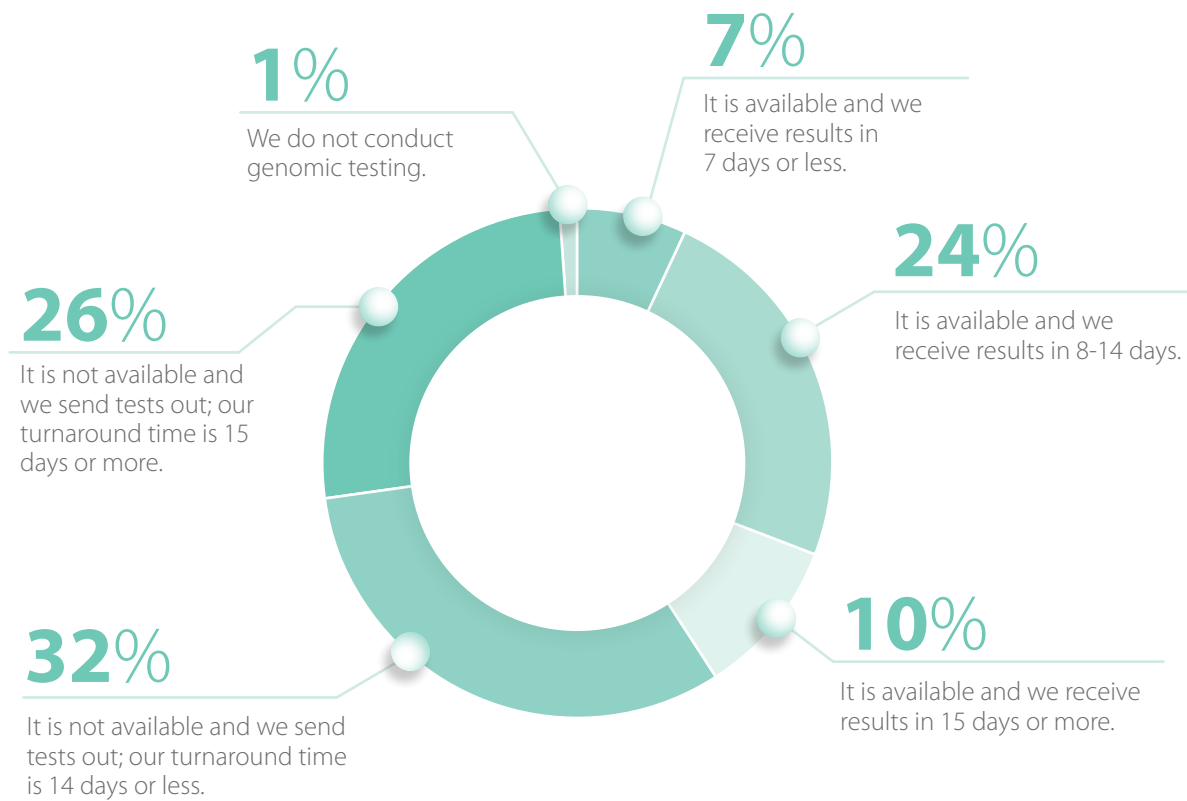
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ABOUT **1in4** PARTICIPANTS SAID THEY ANTICIPATE STARTING TO USE GENOMIC TESTING IN THE YEAR AHEAD.



Local availability of genomic testing and turnaround times for results are highly varied.

Which of the following statements best describes the availability of genomic testing at your local institution?



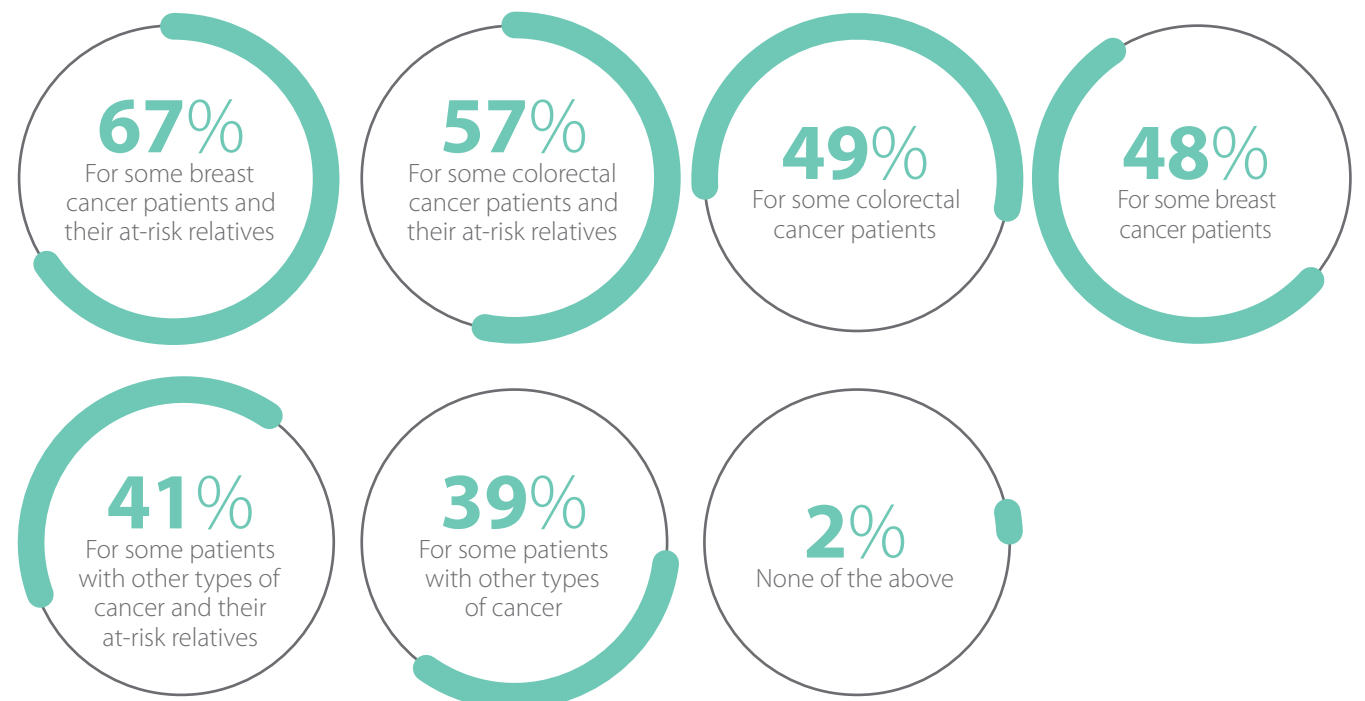
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ABOUT **1 in 4** } ONCOLOGISTS SURVEYED SAID TURNAROUND TIME FOR GENOMIC TESTING IS **15 DAYS OR MORE**

Genomic testing for patients – and at-risk relatives – is a common practice for some cancers.

More than half of responding oncologists say they test at-risk relatives of both breast and colorectal cancer patients.

For which of the following groups does your practice recommend genetic susceptibility testing? (select all that apply)

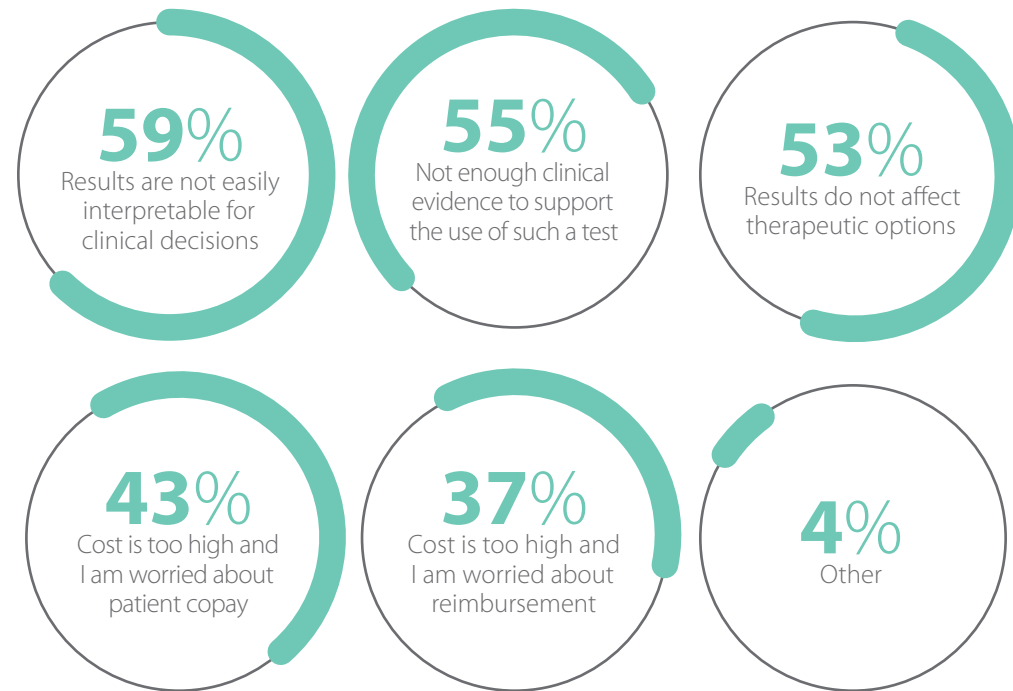


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2/3 } OF PARTICIPATING ONCOLOGISTS TEST BOTH **BREAST-CANCER PATIENTS AND THEIR RELATIVES.**

Challenges in interpreting results was cited as the most common reason for not using comprehensive genomic testing.

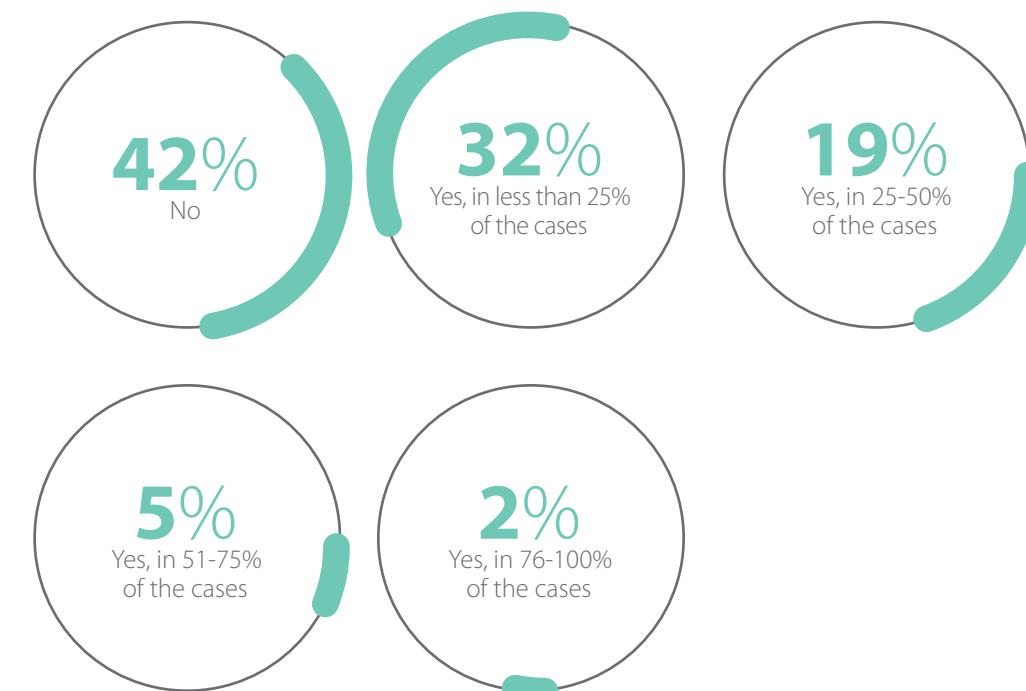
Please indicate why it may be perceived that comprehensive genomic testing is not warranted for most patients? (select the three most compelling reasons)



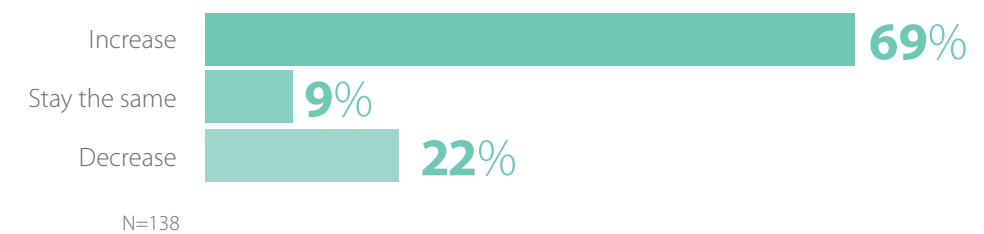
ABOUT **4 in 10** } ONCOLOGISTS ARE CONCERNED ABOUT PATIENT COPAYS FOR GENOMIC TESTING.

More than half of participating oncologists see cost savings in some cases, but overall, they believe genomic tests will increase the cost of cancer care.

In your opinion, does genomic testing lead to cost savings?



On a net basis, what effect do you believe genomic tests will have on oncology healthcare costs in the future?

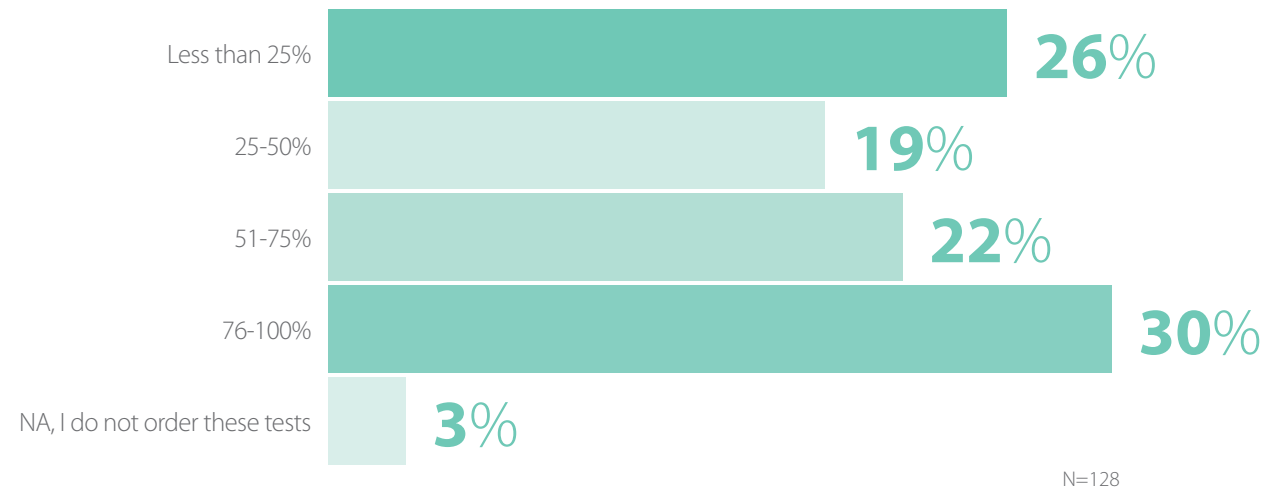


ONLY **22%** } BELIEVE GENOMIC TESTS WILL DECREASE THE COSTS OF ONCOLOGY CARE IN THE FUTURE.

GENOMIC TESTING

Insurance company practices regarding preauthorizations for genomic testing vary widely.

What percentage of the genomic tests that you typically order require preauthorizations?



MORE THAN HALF OF RESPONDENTS SAY PRIOR AUTHORIZATIONS ARE REQUIRED FOR THE **MAJORITY OF GENOMIC TESTS.**





Contributors

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Cardinal Health Specialty Solutions

References

1. <https://www.cdc.gov/genomics/gtesting>
 2. <https://www.ncbi.nlm.nih.gov/gtr>
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Want to learn more?

Let's explore how we can help.
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Visit us online.

Dive deeper into our solutions and services
at cardinalhealth.com/specialtyolutions

Methodology

The research was fielded at three live summit events, hosted by Cardinal Health Specialty Solutions, in February, March and April 2018, using audience response system technology. More than 160 oncologists from a mix of community and hospital-based practices participated in the research.

About Cardinal Health Specialty Solutions

Cardinal Health Specialty Solutions creates opportunity for specialty pharmaceutical manufacturers and providers. Our trusted team of advisors understands the complexities of specialty healthcare, and we draw on our deep expertise to help ensure patients get the therapies they need, when they need them. From supporting manufacturers on the path to successful product approval, commercialization and optimization to delivering the products providers need with the efficiencies they want, we use our experience and expertise to help our customers achieve success and improve specialty care.